



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US99/31210 (22) International Filing Date: 30 December 1999 (30.12.1999) (30) Priority Data: 09/224,396 31 December 1998 (31.12.1998) US (60) Parent Application or Grant RXSITE INCORPORATED [/]; O. MORRISON, Royce [/]; O . OSTER, Jeffrey, B. ; ().	Published	
(54) Title: PROCESS FOR CONSUMER-DIRECTED PRESCRIPTION INFLUENCE AND HEALTH CARE PROFESSIONAL INFORMATION (54) Titre: PROCEDE PERMETTANT D'EXERCER UNE INFLUENCE SUR UNE ORDONNANCE PRESCRITE A UN CONSOMMATEUR ET FACILITANT LA COMMUNICATION D'INFORMATIONS DONNEES PAR DES PROFESSIONNELS SUR LES SOINS DE SANTE		
(57) Abstract <p>There is disclosed a process for facilitating consumer and professional interaction and communication [2250, 2350, 2750, 2850] about products and services that require a professional decision and prescription or authorization before a consumer can purchase or use a particular product or service by a professional, or facilitating the marketing of regulated products by manufacturers to professionals, consumers and health care systems, or providing consumers with a means for influencing decisions of professions and health care systems with respect to providing a product or service and having the product or service available with a particular health care system program.</p> (57) Abrégé <p>L'invention porte sur un procédé visant à faciliter l'interaction et la communication [2250, 2350, 2750, 2850] entre des professionnels et des consommateurs concernant des produits et des services qui nécessitent une décision et une ordonnance ou une autorisation d'un professionnel avant que le client n'achète ou n'utilise un produit ou service particulier, ou faciliter aux fabricants la commercialisation de produits réglementés à des professionnels, des consommateurs et des systèmes de soins de santé, ou fournir à des consommateurs un moyen d'influencer des décisions de professionnels et de systèmes de soins de santé par rapport à la fourniture d'un produit ou service ou un moyen d'obtenir le produit ou service disponible avec un programme spécifique d'un système de soins de santé.</p>		

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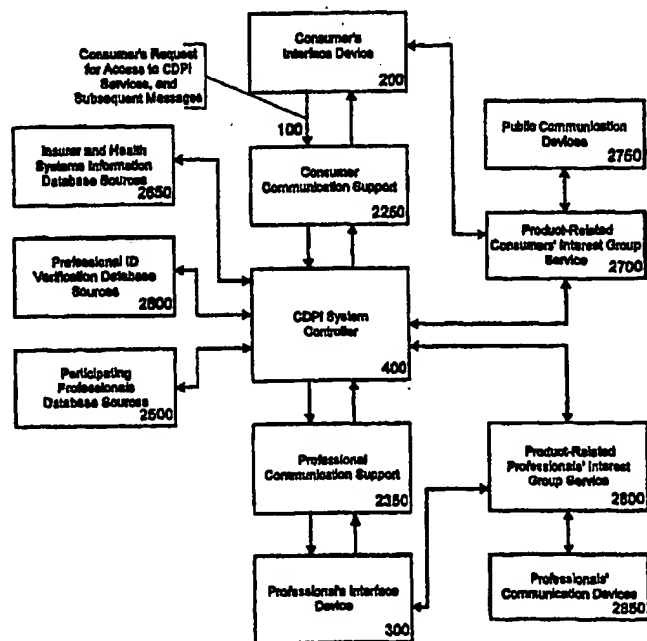
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(21) International Application Number: PCT/US99/31210 (22) International Filing Date: 30 December 1999 (30.12.99) (30) Priority Data: 09/224,396 31 December 1998 (31.12.98) US (71) Applicant: RXSITE INCORPORATED [US/US]; 2808 East Madison, Seattle, WA 98112 (US). (72) Inventor: MORRISON, Royce; 1102 East Shelby Street, Seattle, WA 98102 (US). (74) Agent: OSTER, Jeffrey, B.; Davis Wright Tremaine LLP, 2600 Century Square, 1501 4th Avenue, Seattle, WA 98101-1688 (US).		(81) Designated States: AU, CA, CN, IL, JP, NZ, RU, ZA, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: **PROCESS FOR CONSUMER-DIRECTED PRESCRIPTION INFLUENCE AND HEALTH CARE PROFESSIONAL INFORMATION**

(57) Abstract

There is disclosed a process for facilitating consumer and professional interaction and communication [2250, 2350, 2750, 2850] about products and services that require a professional decision and prescription or authorization before a consumer can purchase or use a particular product or service by a professional, or facilitating the marketing of regulated products by manufacturers to professionals, consumers and health care systems, or providing consumers with a means for influencing decisions of professions and health care systems with respect to providing a product or service and having the product or service available with a particular health care system program.



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Description

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PROCESS FOR CONSUMER-DIRECTED PRESCRIPTION INFLUENCE AND HEALTH CARE PROFESSIONAL INFORMATION

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Technical Field of the Invention

5 The present invention provides a process and an apparatus for (1) facilitating consumer and professional interaction and communication about products and services that require a professional decision before a consumer can purchase or be prescribed a particular product or service by a professional, (2) facilitating the marketing of regulated products by manufacturers to professionals, consumers and health care systems, and (3) providing consumers with a means for influencing decisions of professions and health care systems with respect to providing a product or service and having the product or service available with a particular health care system program.

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Background of the Invention

Health Care Products Markets

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15 Health care products markets are characterized by the legal and/or contractual assignment to health care professionals and/or health care systems of the authority to prescribe, specify, authorize, cover (bear the cost of), restrict, prohibit, or exclude products for use by consumers. For example, a consumer may not independently decide to purchase and use a prescription product; the prerogative to approve or deny access to the product belongs to professionals with prescriptive authority. Further, the availability and/or benefit "coverage" of a particular product within a particular health care system (e.g., Blue Cross of Pennsylvania or Harvard Community Health Plan) may be subject to approval by a Pharmacy and Therapeutics Committee, Formulary Committee, an official of a Pharmacy Benefit Management company, Surgical Care Pathways Committee, Alternative Medicine Committee, etc. Therefore, the consumer's use of or ability to afford a particular product depends upon the decisions and judgements of professionals and others in those health care systems.

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In the relationship between individual consumer and health care professional, the decision to use a product is shared. The professional must approve and prescribe the product or service and the consumer must agree to use it. However, the decision-making process has typically been highly asymmetrical, with the preponderance of information (about the medical condition under treatment and the product or service proposed for use) and initiative being in the sole possession of the professional. The hurried process of the medical consultation often does not allow extensive or even adequate transfer of information, and the consumer's ability to participate in the decision-making process is limited.

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35 Even so, the dynamics of the relationship are undergoing change, with shifts in cultural attitudes about health care relationships and with the advent of information and communications systems which enable consumers to search for and find health care and health product information. Further, the rapid increase in pharmaceutical manufacturers' direct-to-consumer (DTC) marketing activities has heightened consumers' awareness of diagnoses and

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5 treatments, particularly newly marketed treatments. Consumers increasingly gain access to
information about medical diagnosis and about products even before such information has been
received or integrated into practice protocols by individual health care professionals or health
10 care systems.

5 However, in existing health care system relationships, the consumer's ability to
accelerate the consideration of a product and to influence product decisions remains limited by
lack of information, by barriers of time and effort, and by a lack of mechanisms for initiating
action.

15 In the relationship between individual consumer and professional, the interested,
10 assertive consumer may attempt, before making an appointment, to determine whether the
professional is knowledgeable about the product of interest, but the communication and
response processes of typical professional offices do not provide confident, satisfactory
20 answers to that question. The consumer may make an appointment to consult with the
professional about a health problem and the possible use of a particular product, but
15 information about the reason for the appointment is not evident to the professional until the
scheduled visit, allowing no time for the professional to prepare. If the consumer has brought
25 printed information to the visit, the hurried setting does not permit the professional time to
review, consider, integrate, and use the information, and the professional (as a highly trained
individual) may feel that the consumer-provided information is not adequate for the purpose.
20 The professional, unprepared to discuss the product, may feel embarrassed and/or negatively
30 biased against it. The consumer may feel that his or her request was overly assertive and that
the relationship is strained. At best, the professional may agree to make the effort to
investigate the topic, and the consumer must return for another consultation. The consumer
largely loses the time, effort, and financial cost of the consultation. Therefore, there is a need
25 to improve this relationship when the consumer has taken steps to research treatments for his
or her health status.

The consumer may find that the particular health care system or insurer has not yet
considered the product for inclusion in its restricted formulary, or has considered and rejected
it for reasons that are unavailable, unexplained or unconvincing to the consumer. The
40 individual consumer's expression of preference has little or no impact on decision-makers at a
30 particular health care system or insurer. Consumers in the same health care system with
similar concerns are unable, without inordinate effort and expense (such as bulk mailings,
published notices, or redirection of a meeting agenda), to identify each other and are
45 consequently unable to form an interest group to aggregate and exert their pooled influence.

35 Therefore, in the existing health products market system, (1) a consumer may become
interested in the possible use of a product, and not be able to anticipate the particular
information needs of the health care professional; or (2) prefer that the manufacturer and/or
50 other sources of information provide information and information choices to the health care
professional in anticipation of consultation; or (3) wish to identify and gain access to health

5 professionals who are already informed about and prepared to discuss and consider the possible use of the product; or (4) wish to express preferences regarding products, to aggregate, report and be aware of the preferences of other consumers, to participate in a related interest group's activities, and to increase the influence of consumers' preferences on product decisions
10 in the consumer's health care system.

At present, there are inadequate means for consumers to effect any of the four foregoing activities. Thus, there is a need in the art to devise a process to facilitate the foregoing four activities.

The implications of the above four activities can be further developed as follows:

- 10 (1) The consumer may not be able to anticipate the particular information needs of the health care professional.

The professional may already be well informed and need only information about what has changed in light of recently reported clinical experience. The professional may have partial recall of information about the product and need to review or update information. The professional may be uninformed about the product (particularly if it is new or used for rarely encountered disease states) and need to learn about it and to review the pathophysiology of the disease states for which the product might be appropriately prescribed. The professional may need to present new information about the product to a formulary committee, to seek its admission to the health care system's pharmacy formulary. In any case, the consumer has limited ability to assess or anticipate the professional's information needs.

At present, the health care products market system does not conveniently provide information and service resources from manufacturers or other information sources for selection by a health care professional responding to a consumer's interest in a specific product. There is a need in the art to do so.

- 25 (2) The consumer may prefer that the manufacturer or other information provider inform and suggest further information and service choices to the health care professional, in anticipation of consultation between the consumer and the professional.

A consumer may feel that his or her efforts to gather and present information to the professional will be less effective than the professional's own choices of information from conveniently available resources. A consumer may feel uncomfortable providing information directly or being identified to the professional. Accordingly, a consumer may prefer to direct the manufacturer or other information providers to inform the professional that a consumer is interested in the product and to offer more product-related information to the professional. Prompted by notice of a consumer's interest in a product, a professional may then choose to draw on the services provided by the manufacturer or other information provider, or seek information elsewhere. The professional can then be prepared for discussion and shared decision-making with the consumer. In any case, the knowledge that a consumer is interested in the product and will soon be consulting about it will help the professional in making best use of time and effort expended for continuing education. The use of available information

resources and the need to apply them in professional practice can occur in quick succession, positively reinforcing learning, easing stress for the professional, increasing satisfaction for the consumer, and improving the effectiveness of marketing efforts for the manufacturer.

At present, shared-decision market systems do not conveniently facilitate such requests by consumers for informational marketing by manufacturers or provision of information by other sources to individual health care professionals. There is a need in the art to do so.

(3) The consumer may wish to identify and gain access to health professionals who are already informed about and prepared to discuss and consider the possible use of the product.

For example, a consumer interested in a new drug product may not have a relationship with a primary or specialty physician and may wish to identify a physician who is already informed about the new drug product. While knowledge of a physician's specialty increases the likelihood of identifying a physician who is prepared to consult about the particular product, it is not entirely reliable, particularly in the case of a new product and less than fully effective marketing efforts of manufacturers. Further, while it is possible for consumers to telephone professionals' offices to inquire about knowledge of a particular product, a professional's office staff are more likely to give nonspecific assurances than to interrupt the professional's work to pose the specific question. While the manufacturer of a new pharmaceutical product may be motivated to provide information about physicians who have been informed about the product or service, convenient, Internet-mediated systems for responding to consumer requests for such information do not exist with manufacturers of pharmaceutical products and could open up regulatory scrutiny if offered by manufacturers. There is a need in the art to conveniently provide this information to consumers.

(4) The consumer may wish to express preferences regarding products or services, to aggregate, report and be aware of the preferences of other consumers, to participate in a related interest group's activities, and to increase the influence of consumer preferences on product decisions in the consumer's health care system or insurer.

Individual consumers may become interested in a product, but they do not know how many other consumers in the same health care system or insurance plan share a similar interest in that product, and they have no convenient way of communicating aggregated information about preferences to physicians, administrators, and committees. This makes it difficult for consumers, as a class, to influence the decisions of health care systems and insurers regarding pharmacy formulary and other product decisions.

At present, health care product market systems do not conveniently facilitate such expression, aggregation, and reporting of preferences by consumers, nor the mutual identification of consumers for interest group activity. There is a need in the art to do so.

Regulatory Constraints on Provision of Information by Manufacturers

A further limitation of the existing health care prescription drug market is that, while manufacturers are motivated to provide comprehensive information to health care professionals. Professionals are trained to assess such information, regulatory constraints

5 applied by the U.S. Food and Drug Administration (FDA) preclude provision of certain
categories of information about prescription products. Specifically, though uses of drugs for
10 which the FDA has not granted official approval are legally and ethically employed by
professionals and consumers, manufacturers are not allowed to provide information about such
5 uses to professionals, with minor exceptions. This makes it more difficult for consumers and
professionals to obtain such information and makes it impossible for manufacturers to respond
to a consumer's request or a professional's request to provide complete information from the
15 medical literature. There is a need in the art to allow the dissemination of information to
professionals, trained to evaluate such information, but still within regulatory guidelines and
10 while avoiding regulatory noncompliance by manufacturers.

In addition, the FDA is a regulatory agency that functions to approve (or deny)
20 marketing of products (drugs or devices) according to a complex regulatory scheme set forth in
21 C.F.R. In general, the manufacturer submits an appropriate product application (such as a
New Drug Application or NDA for a drug, or a premarket application or pma for a device) and
15 the FDA only communicates with the manufacturer. The result of product marketing approval
is that the indications and label copy of approved products are negotiated between the FDA
25 and the manufacturer. The FDA then regulates the manufacturer to comply with approved
market parameters and monitors submission of adverse incidents reports that are submitted by
the manufacturers or sometimes by professionals. The consumers do not have a voice in this
20 process of either product approval or the extent of approved uses for an approved product.
30 There is a need to provide a means for the consumer to have a greater voice and influence in
this regulatory process as it is designed to be in the consumers' benefit.

Similarly, Health and Human Services (HHS) at the Federal level and insurance
commissioners on a State level are empowered to regulate Federal health care systems, such as
35 25 Medicare and Medicaid, and state health care systems, such as HMOs, in regulating those
products and services that can and cannot be in a formulary or subject to reimbursement.
Again, the consumer does not have a voice or at least a significant voice in influencing such
regulatory directives. Again, there is a need to provide a means for the consumer to have a
40 greater voice and influence in this regulatory process as it directly impacts the consumers'
30 benefits.

Networked Information Systems

Networked personal computer systems are revolutionizing processes of information,
45 communication, and commercial transactions. While these changes have been developing for
three decades or more, they are rapidly advancing due to the recent advent of unrestricted
35 public access to the Internet, combined with the availability of inexpensive and powerful
personal computer systems with highly functional software systems supporting easy use of the
Internet's increasingly valuable resources. While the present invention's uses are applicable to
50 any networked information system to which consumers have ready access, the dominant
system for practical purposes is the Internet.

5 The Internet is an electronic communications system based on standards and protocols
which are widely accepted and allow users with a variety of computer hardware and software
systems to gain access to worldwide information and communications resources. Millions of
10 commercial, governmental, and noncommercial entities have created Internet websites offering
5 information and communication opportunities to users. Pharmaceutical companies, for
example, create product-specific websites for virtually every new pharmaceutical product and
widely advertise the availability of those websites without access restrictions. Users may
15 connect with websites by entry of specific Internet website addresses. In the case of unknown
address or unknown resources, Internet search engine services allow users to find information
10 about almost any topic of interest. Health-related Internet information resources have high
rates of use by consumers and professionals.

20 Therefore, there is a need in the art to utilize the efficiencies created by the Internet to
meet the foregoing needs of consumers, professionals and manufacturers regarding the
dissemination of product information within the boundaries of regulatory compliance. The
15 present invention addresses the foregoing needs.

Summary of the Invention

25 The present invention provides a process for (1) facilitating consumer and professional
interaction and communication about products and services that require a professional decision
before a consumer can purchase or be prescribed a particular product or service by a
20 professional, or (2) facilitating the marketing of regulated products by manufacturers to
30 professionals, consumers and health care systems, or (3) providing consumers with a means for
influencing decisions of professions and health care systems with respect to providing a
product or service and having the product or service available with a particular health care
system program, the process comprising the steps of:

- 35 25 (a) providing a direct-to-consumer and professional health care product or service
information source having a connection or a link to a transaction-based consumer and
manufacturer product or service communication/transaction service;
- 40 (b) providing the transaction-based consumer and manufacturer product or service a
30 communication service having a consumer transaction menu listing potential transactions
selected from the group consisting of (i) informing a professional about a consumer's interest
in a particular product, service or disease state, (ii) providing the professional with information
about the particular product or service, (iii) providing the consumer with identification of
45 professionals who have been informed about a particular product or service, (iv) providing
consumers with a means for communicating health care product or service preferences and
35 desires to health care systems and professionals who have the means or authority to prescribe,
specify, authorize, cover (bear the cost of), restrict, prohibit or exclude products for use by
consumers and reimbursing for covering the costs of such health care products and services,
50 (v) providing the means for consumer aggregations to form interest groups to influence health
care systems and professionals with regard to consumer availability of products and services,

5 (vi) providing the means for the consumer to communicate with appropriate governmental regulators or administrators of such products or services, and combinations thereof; and

(c) allowing a consumer an ability to complete one or a plurality of transactions.

10 Preferably, the transaction-based consumer and manufacturer product or service

5 communication service further provides the consumer the means for providing his or her identity to manufacturers, professionals and health care systems or not providing his or her identity to any or all of the selected manufacturers, professionals and health care systems.

15 Preferably, the transaction of informing the professional about a consumer's interest in a particular product, service or disease state provides the professional with information from the manufacturer of the product or service, such information from the manufacturer having been
10 approved by an appropriate regulatory agency. Most preferably, such information is supplemented by product coupons or vouchers for consumer use, and provision of such materials is coordinated with provision of product samples to the consumer's identified health
20 care professional by mail or by a manufacturer's sales representative. Most preferably, the information provided to the health care professional is supplemented by independent (of
15 manufacturers) research concerning the product, service or disease state from published medical literature. Preferably, the system will also enable the manufacturer to accomplish the transaction of informing the health care professional about the immediate interest of a
25 consumer (identified or not) in a product, service, or disease state on the basis of the consumer's indication of interest and with information about the identity of the consumer's
20 health care professional (obtained by the consumer's direct provision of that information or from another source such as a health system database), even if the consumer does not overtly direct the provision of information to the professional. In such instance, the transaction of
30 informing the identified health care professional would proceed on the basis of implied consumer-direction.

35 Preferably, the transaction (ii) to provide information about a consumer's interest in a particular product, service or disease state further comprises the step of consulting a manufacturer's/products database to determine if a participating manufacturer subscribes to the transactions service. Preferably, the transaction (ii) to provide information about a consumer's
40 interest in a particular product, service or disease state further comprises the step of consulting a professionals database to determine if a professional selected by the consumer is known in the database as a licensed professional able to provide the service or prescribe the product
45 selected.

35 Preferably, the transaction (iii) to provide the consumer with a list of professionals who have been informed about the selected product or service further comprises the step of consulting a participating professionals database to find a list of professionals who have received information about the selected product from its manufacturer, are prepared to provide
50 consultation, and have indicated their willingness to participate in the referral system. Most preferably, the list or professionals provided to the consumer are further selected on the basis

5 of geographic area taken from addresses listed in the professionals database and other criteria (e.g., specialty, gender, language, ability, etc.).

10 Preferably, the transaction (iv) to inform either or both of a consumer's health care professional or health care system (e.g., health insurance plan, HMO etc.) of the consumer's
5 desire and need to have a particular product or service available to the consumer under the consumer's health care system, further comprises the step of consulting with a health insurer/systems database to insure that the consumer's wishes are correctly transmitted to the correct recipient. Preferably, the transaction (v) to make other consumers in a relevant interest
15 group aware of a product or service and aggregate such consumers into an interest group further comprises the step of identifying interested consumers to each other and facilitating communication between them but not necessarily to the health care system or health care professional.

20 The present invention further provides an apparatus or server system for implementing the transaction-based consumer and manufacturer product or service communication service
15 over a wide area network or over telephone and mail means of communication, wherein the server system comprises a central processing unit, ROM, RAM, and a data storage device, wherein the data storage device comprises one or a plurality of databases selected from the group consisting of a manufacturers/products database, a consumers database, a professionals database, a participating professionals database, a health insurers/systems database, and
25 combinations thereof. Preferably, the apparatus or server system data storage device is able to complete transactions i-vi and comprises each of the manufacturers/products database, the consumers database, the professionals database, the participating professionals database, and the health insurers/systems database. Most preferably, the apparatus or server system data storage device further comprises one or a plurality of a sessions database, a transactions
30 database, a CDPI process reference database, and combinations thereof.

35 **Brief Description of the Drawings**

Figure 1 illustrates a hardware configuration for a Consumer-Directed Prescription Influence Service and Information System (CDPI system).

40 Figure 2 shows a Consumer's Interface Device in block diagram format.

30 Figure 3 shows a Professional's Interface Device in a block diagram format.

Figure 4 illustrates a CDPI System Controller in a block diagram format showing an embodiment of the computer controller of the consumer-directed prescription influence service and information system.

45 Figure 5 shows a CDPI Internet Interface flowchart illustrating an embodiment having the logical and event sequencing of an interactive session of a consumer and the CDPI system.

50 Figure 6 shows a Consumer-Directed "Inform Doctor" Transaction, illustrating how a consumer interacts with the CDPI system to direct provision of product information and consumer-specific information to a designated professional (i.e., doctor).

Figure 7 shows a Consumer-Directed "Report Informed Doctors" Transaction process,

5 showing how a consumer interacts with the CDPI system to direct reporting of product-informed doctors who meet the consumer's selection criteria.

10 Figure 8 shows a Consumer-Directed "Express Preference" Transaction, showing how a consumer interacts with the CDPI system to direct expression of product- and disease state-related consumer preferences, how a consumer directs communication of those preferences, 5 and how a consumer directs the CDPI system's subsequent routing of related messages to the professional or health care system.

15 Figure 9 shows a CDPI System process flow chart with consumer ID and message functions, showing how a consumer interacts with the CDPI system to direct provision of the consumer's identification information, and/or the consumer's message, to designated recipients. 10

20 Figure 10 shows a CDPI System, wherein a consumer chooses to receive subsequent topical messages through the CDPI system, showing how a consumer interacts with the CDPI system to direct forwarding of messages to the consumer at an address specified by the consumer. 15

25 Figure 11 shows a reference database query process, wherein the CDPI Central Controller queries external reference database systems with or without the involvement of human-to-computer interfaces.

Detailed Description of the Invention

20 As will be made clear below, the general availability of personal computers and of the Internet and the advent of the present invention make possible mechanisms to enable and encourage influential consumer-directed transactions of the kinds described above and to increase the efficiencies of health care professionals' education activities and of manufacturers' marketing activities. 30

35 Definitions

Health Care Products shall mean primarily prescription-based therapeutic agents, medical devices, and services (e.g., physical therapy, surgical placement of appliances, etc.).

40 Consumers shall mean to individual consumers or potential consumers of health care products and services, also to the responsible guardians of minors or of legally incompetent individuals, and also to the owners of animals receiving or potentially receiving veterinary care. 30

45 Professionals shall mean all health care professionals who have prescriptive authority (such as physicians, nurse practitioners, physicians' assistants, dentists, and veterinarians) or have influence (such as nurses, therapists, pharmacists, and chiropractors) in the choice and prescription of products. 35

50 Health Care Systems shall mean the administrative or business units in the vast network of managed care and insurance reimbursement systems and includes, for example, health maintenance organizations (HMOs), managed care providers, health insurance programs, pharmacy benefit managers, and other provider or payor based programs that can control, in

any way, the dispensing of health care services.

Manufacturer shall mean a manufacturer of a drug or device or the provider of a service.

Product shall be understood to include reference to a drug or drug-containing product, a device, a process, or a service.

Health Products Marketing shall mean the regulated (*e.g.*, by the FDA) means of advertising, promoting, distributing, and selling drugs, devices, and services used in the health care of consumers.

Doctor shall mean any health care professional with prescriptive authority or influence for health care products or services.

Governmental Regulators and Governmental Administrators refer to those individuals who either regulate or approve (or deny) the marketing of products by manufacturers or services (*e.g.*, Food and Drug Administration), or those State (Insurance Commissioner) or Federal (Health and Human Services) agencies that regulate which products or services must be provided or reimbursed in health care systems (*e.g.*, HMOs) or federal health benefit systems (*e.g.*, Medicare and Medicaid).

Objects

In health care systems and health care products markets, there are established methods of transacting various kinds of information transfer, communications, and commerce between the various parties of those systems. Therefore, the objectives of the present invention include:

- (1) enabling the consumer in health care products markets to conveniently direct manufacturers and other parties to provide communications and information about products and about related information and services to the attention of professionals designated by the consumers;
- (2) enabling the consumer in health care products markets to conveniently identify professionals who are available to provide consultation to them and are already prepared to consult about the appropriate use of specified products;
- (3) enabling the consumer in health care products markets to conveniently express preferences regarding products, to aggregate such expressions of preferences with other consumers, to be informed of the results of such aggregation, to establish communication with other interested consumers, to report such results publicly and to professionals health care systems and governmental regulators and administrators for the purpose of influencing deliberations and decisions regarding products;
- (4) enabling the consumer to accomplish such transactions either anonymously or confidentially or openly;
- (5) enabling manufacturers and other parties to direct product-related communications and information and services (such as sample fulfillment) to professionals at times when the professionals' need for and responsiveness to such communications, information and services is demonstrably immediate;

5 (6) enabling manufacturers and other parties to accomplish such transactions, coordinated with their other marketing and information provision activities (particularly Internet-mediated activities) while achieving the advantages of outsourcing the transaction processes to a separate business organization;

10 5 (7) enabling professionals to be apprised of the consumer's needs for consultation about particular products prior to the times of those consultations;

15 (8) enabling professionals to optimally match the timing of their continuing education activities, related to the use of particular products, with the timing of consultations with consumers;

20 10 (9) enabling professionals to conveniently obtain information and services provided by product manufacturers and also information which cannot, because of regulatory restrictions, be provided directly to professionals by manufacturers; and

25 (10) providing services of such value to consumers, professionals, manufacturers, and others that the CDPI system will have a strong basis for commercial success.

30 15 In a further preferred embodiment, consumers who have become interested in the possible use of a health care product and who depend on health care insurers, systems, or professionals for financial payment, approval, consultation, or prescription in order to make use of the product are enabled by the inventive process to exert influence upon the decision-making processes of such insurers, health care systems, or professionals. Simultaneously, through enabling the influence of interested consumers, the inventive process improves the marketing processes of the manufacturer or provider of such product. Simultaneously, by closely matching the presentation of product-related information and marketing services with the timing of an actual clinical need for consideration of the product or service, the inventive process improves continuing education and decision-making processes of health care professionals. By facilitating referral of interested consumers to professionals who are informed and ready to provide consultation regarding the possible use of a product, the inventive process improves convenient access to consultation for consumers, efficient learning, clinical practice, and business for professionals, and efficient marketing for manufacturers. By establishing a source of products-related information which is integrated with these above-mentioned activities and which includes preparation of information through independent authorship and editorial processes, and which includes presentation of such information to segregate it from information provided by product manufacturers, the inventive process creates an accessible means for enabling consumers and professionals to conveniently obtain, evaluate, and act upon information about non-approved uses for products. By enabling the reporting to health care systems of aggregated consumers' preferences and communications regarding a product or service, the inventive process improves consumer participation and consideration of consumer preferences in health care systems' decision-making processes.

50 In a preferred embodiment of the inventive process, the interactions between the CDPI system and the consumer are accomplished through the consumer's electronic network (e.g.,

Internet) access, appropriate (e.g., graphical) interface, and personal computer system (including software and hardware) in communication with the CDPI system's network-mediated services and information systems. The intent of the CDPI system is to enable consumers to direct prescription influence transactions. Moreover, as consumers and the professionals and/or health care systems they specify may not share common access to an electronic network communications system, the inventive process fulfills consumer-directed transactions through a variety of media appropriate to the communications capabilities of the specified professionals or health care systems.

(a) Enable the Consumer to Become Informed About a Product.

In a preferred embodiment, the CDPI system provides product-related informational content which is found by consumers using commonly-available Internet web browser software interfaces in personal computers or other interactive devices which are connected to the Internet. The information is drawn from sources including the manufacturer of the product, other authoritative authors and organizations, and content produced or commissioned by the CDPI system. Consumers find such information and the CDPI website(s) providing the information by performing general Internet searches (as through portal sites such as Yahoo!, Netscape, Excite, or Alta Vista) using designated key words (product name or category, disease state, etc.), or by coming directly to the CDPI website in response to marketing of CDPI website(s), or by returning to a previously visited CDPI website, or in response to a recommendation from another consumer or a health care professional. Alternatively, the CDPI website is provided in conjunction with or linked from a manufacturer's product-specific website, to which consumers have come in response to the manufacturer's direct-to-consumer product marketing. Further, different computerized information networks and devices (i.e., other than the Internet and personal computers with Internet browsers) may be used to effect access to a CDPI system information source. Moreover, despite their inefficiency as compared with Internet-mediated communication, voice telephony, written/printed (e.g., mailed), and other methods of information storage, display, and communication are employed to effect the access of consumer to information about a product.

(b) Enable the Consumer to Become Informed About the Availability of Consumer-Directed Prescription Influence Services for that Product.

When the consumer has gained access to information about a product through a particular medium (as described above in (a)) and has become interested in the possible use of the product for treatment of a disease state or health problem, the same or different medium is employed to inform the consumer about the CDPI services which are available for that product. In a preferred embodiment, this occurs immediately and through the same medium used by the consumer to find and/or receive product information. For example, the consumer who has come to a CDPI website or a manufacturer's product-specific website is presented with information about CDPI services in the course of viewing information about the product. Or, a consumer calling a toll-free "1-800" telephone number for product information hears

information about CDPI services. It also will be possible to use a different medium for product information and offering CDPI services. For example, a consumer who has come to a product-related website may indicate interest in subsequently available information and may give his/her email address or postal mail address, and a message about CDPI services may be sent to that address, electronically or in hard copy. Conversely, a consumer who has requested "hard copy" of product information, by mailing in a postcard associated with a magazine advertisement and giving his/her email address, may be sent a message about CDPI services in more rapid, Internet-based form.

(c) Enable the Consumer to Choose to Direct One or More Prescription Influence Service Activity.

Once informed about the availability of CDPI services, the consumer is offered the opportunity to direct the transaction of one or more of those services. In a preferred embodiment, this occurs immediately and through the same medium as used for steps (a) and (b). For example, the consumer who has received product and CDPI service information from a product-related website or websites may immediately choose to use the "inform my professional" service, using the interactivity features of the website(s) and his/her Internet access system (computer, software, Internet service connection, and browser). Prompted by the website "Do you want your professional to be informed about this product and about your plan to make an appointment for consultation about your possible use of it?" the consumer will respond "yes" and then directs the specific transaction between the CDPI system and the professional. Alternatively, email, postal mail, voice telephone, and other communication methods are used to communicate with a consumer who has indicated (through any medium) an interest in CDPI services and to effect the offer, choice, and consumer direction of the transaction.

(d) Enable the Consumer to State which Potential Use of a Product is Pertinent to His or Her Interest.

Once the consumer directs the CDPI system to inform a specified professional about a specified product in anticipation of the consumer's consultation with that professional, the inventive process provides to the professional information about all of the product's possible uses. However, in a preferred embodiment, the CDPI system prompts the consumer to indicate the disease state or health problem for which that consumer is interested in using the product. This allows the inventive process to provide more specific information to the professional, reducing the time and effort required for the professional to prepare for consultation, reducing the cost of providing information (particularly hard-copy, postal-mailed information), and increasing the CDPI system's and manufacturer's ability to respond to consumers' and professionals' needs for information, education, and marketing activities related to particular disease states and health problems. Such specificity allows the inventive process (CDPI system) to facilitate formation of consumer interest groups related to specific disease states and health problems and provides the manufacturer better market research information.

(e) Enable the Consumer to Provide Information to Identify a Health Care Professional.

The inventive process optionally comprises a consumer-directed "inform my professional" transaction feature. If such an optional feature is selected by the consumer, the CDPI system will need the consumer's identification of the professional. In a preferred embodiment, the consumer will use the same medium used for steps (a) through (d), or at least steps (b) through (d), to provide this information immediately and allow for verification of identification (see step (f), below) of the professional. For example, the consumer continues interactive use of the product-related website and, after choosing to direct the "inform my professional" transaction and giving disease state information, enters professional identifying information (e.g., name, city, state, address, and/or telephone number) sufficient to identify the professional. Alternatively, the consumer may give information to identify the professional verbally by telephone or in written form by postal mail.

(f) Provide for Verification of the Identifying and Addressing Information for a Professional Identified by a Consumer.

If optional step (e) is utilized by the consumer to "inform my professional" transaction, the CDPI system verifies that the consumer's identification of the professional does, in fact, specify a single individual professional or *bona fide* group of professionals practicing together. Such verification compares the information provided with a valid database of professionals. A consumer may give insufficient identifying information. For example, a consumer's identification of his or her professional as "Dr. Smith" in "New York" will not be adequate for individual identification and appropriate fulfillment of the transaction directed by the consumer. A consumer may give erroneous information. For example, a misspelled name, a nickname instead of professional name, an outdated address or telephone number, a mistaken recollection of city location, etc., could preclude accurate identification. In a preferred embodiment, the consumer uses the same medium used for steps (a) through (d), or at least (b) through (d), to provide this information immediately and to allow for immediate, real-time verification of the professional's identity. For example, the American Medical Association's database of doctors of medicine and osteopathy is carefully maintained and updated for accuracy and is available for use in automated and on-line information systems. Real-time, automated reference of the CDPI system controller to that (or a similarly comprehensive and accurate) database allows the system to confirm positive individual identification of the specified professional or, failing that, to prompt the consumer to give additional information, to correct erroneous information, or to select from a list of professionals whose database information most closely matches the information given by the consumer. This allows a positive identification of the specified professional and the professional's address information while the consumer is still in real-time interaction with the CDPI system. Another real-time embodiment of this function would have a consumer in electronic or telephone communication with a CDPI staff person who would refer to electronic or printed database(s) and ask questions by electronic (e.g. through a website interface or email, etc.) communications or

5 telephone to accomplish positive, individual identification of the professional. Further, an
additional embodiment of the inventive process uses communication of information from the
consumer by any of several media (Internet website, email, postal mail, voice message, etc.)
10 followed by delayed processes (automated and/or staff action) to verify positive, individual
5 identification. Such delayed processes require reestablishment of communication with the
consumer to correct ambiguous or erroneous identifying information and, in cases of inability
to communicate with the consumer, can result in failures of identification and inability to
15 notify the consumer of the failed transaction.

(g) Enable the Consumer to State the Time Frame in which He or She Expects to Consult
10 with the Identified Professional about the Product and Product Use of Interest to the Consumer.

In effecting the consumer-directed "inform my professional" transaction, the CDPI
system will best meet the need for timely provision of information to the professional if the
20 consumer accurately specifies the time when he or she will have an appointment to consult
with the professional about the possible use of the product. Through experience in and
15 following many such transactions, the CDPI system will determine the optimal timing for
communicating product information to a professional in anticipation of consultation with the
25 consumer, by measuring rates of use of materials, learning efficiency, consumer satisfaction
with professional preparation for consultation, effect on prescription behavior, etc. If optimal
timing for postal mailing were known to be two weeks prior to the anticipated appointment, the
20 system would effect mailing at that optimal time. In a preferred embodiment, the consumer
will use the same medium used for steps (a) through (f) to provide this information
30 immediately.

(h) Enable the Consumer to Review and Correct the Information Provided by the
Consumer.

35 This optional step first requires that the consumer have provided information to the
CDPI system. The system will immediately communicate to the consumer (e.g., by display
through an Internet browser interface) the information and directions provided by the
consumer, for review and confirmation prior to effecting the transaction. This allows the
40 consumer to reconsider, to correct or change any information, and to give final approval for the
30 transaction. In embodiments of the system which do not provide real-time interactivity,
verification, and confirmation, this step is less feasible. For example, an embodiment using
postal mail for consumer requests and system responses would involve unavoidable delays and
perhaps high rates of consumer failure to respond to confirmatory mailings.

45 (i) Provide Cautionary Information Regarding the Responsibility of Health Care
35 Professionals to Exercise Independent Professional Judgement in the Diagnosis of Disease and
the Authorization or Prescription of Products for Treatment.

As an optional step and in concern for regulations, the inventive process can require
50 acknowledgement of above-noted cautionary information and requirement of the role of health
care providers and acceptance of terms and conditions of use of CDPI services. In effecting

5 the consumer-directed "inform professional" or "refer to professionals" transactions, the CDPI
system avoids giving or implying any warranty as to the professional's services or response to
the consumer's inquiry about the product of interest. That is, the CDPI system clearly
10 communicates to the consumer that health care professionals have an overriding duty to make
5 independent professional judgements about the disease states or health problems of the
consumer and about the appropriate use of prescription products for treatment of the consumer,
that professionals conduct their own business and professional practices independently of the
CDPI system, and that the CDPI system cannot be responsible for the judgements, actions, or
15 omissions of professionals. Similarly, the inventive process informs consumers of their
responsibility for ascertaining that the training, experience, and other characteristics of
10 professionals are appropriate to the individual consumer's interests and needs, to the effect that
the system cannot be responsible for the judgements, actions, or omissions of professionals.
20 These cautionary communications effect compliance of the CDPI system with the ethical and
statutory separation of health care professionals, in their relationships with consumers, from
15 involvement with or obligations to third parties such as the CDPI system, professionals, health
care systems, or product manufacturers. The system also cautions the consumer that the
25 system does not accept responsibility for any damages (e.g., the cost of consultation with
professional) arising out of a professional's decision regarding product prescription nor any
damages arising out of system failure to effect a consumer-directed transaction. Consumer
20 acknowledgement of reading and accepting these disclaimers as conditions of use of the CDPI
system will be a precondition for concluding a consumer-directed transaction. These
30 communications protect the CDPI system from claims of responsibility for any particular
outcome of the consumer's direction of the system to effect a transaction or a particular
outcome of a transaction. In a preferred embodiment of the present invention, these
35 communications will occur through the same medium used for and at the same time as the
consumer's interactive accomplishment of some or all of steps (a) through (g).

(j) Enable the Consumer to Identify Himself or Herself, by Name or by Other Identifying
Information, to the Specified Health Care Professional.

40 In effecting the consumer-directed "inform my professional" transaction, the CDPI
30 system optionally provides more personalized service to the consumer and useful information
to the specified professional by enabling the consumer to identify himself or herself to the
professional. This communication service option uses a highly effective method and apparatus
45 to maintain the consumer's privacy and confidentiality in protecting against disclosure of
identity and disease state or health problem information to unintended recipients of information
35 and in protecting against fraudulent communications of one consumer in place of or about
another. One approach to concealing identity will be to avoid actual disclosure of identity by
the consumer to the CDPI system. This is accomplished by having the consumer provide a
50 name/identifier (such as initials and medical record number) which will identify the consumer
to the specified professional but not to other persons. Alternatively, the consumer can provide

an actual name and some separate identifier (such as a medical record number or other information known to the professional and/or a secure intermediary system), allowing positive identification of the consumer as the director of the transaction and author of any associated communication to the professional. To protect identity information as it is sent by consumer to the CDPI system and by the system to the specified professional, secure, encrypted electronic communication (in the preferred embodiment) is used. Alternatively, secure postal or commercial mail may be used for one or both communications.

(k) Enable the Consumer to Create a Message to be Delivered to the Identified Professional.

To optimally match the consumer's need with the professional's receipt and use of product information, the CDPI system may optionally enable the consumer to create a message to be delivered to the professional with the product information. For example, Mr. Smith might wish to mention to Dr. Jones that his Parkinsonian tremor has been intermittently disabling and that he is interested in Dr. Jones' thoughts about a new anti-Parkinsonian drug product. The inventive process creates a mechanism that enables and encourages a consumer to attempt to influence the professional's consideration of prescription of a particular product and provides a coordinated mechanism for effecting that influence, including communication of messages. In a preferred embodiment, the consumer can use his/her Internet browser interface to enter such a message as text or voice email to be securely transmitted with the consumer's identifying information to the CDPI system. Alternatively, the consumer can write a message to be sent to the CDPI system by postal mail or can speak a message to be recorded and/or transcribed by the CDPI system. The system then communicates the message in a manner appropriate to the specified professional's communications capabilities and preferences, such as email, postal mail, voicemail, etc.

(l) Communicate the Information (Product, Disease State or Health Problem, Consumer Identification, Consumer Message, Anticipated Time of Consumer's Consultation with Professional) Provided by the Consumer to the Specified Professional, and Provide Related Information from the Product's Manufacturer and other Sources, as Requested by the Consumer and as Deemed Appropriate by the Manufacturer or Other Sources.

The inventive process fulfills the consumer-directed "inform my professional" request by communicating information to the specified professional in a manner appropriate to the professional's communications capabilities and preferences. In a preferred embodiment, the professional's communication capabilities, preferences, and addresses are in a CDPI system database, allowing electronic communication (e.g., email) communication with those professionals who prefer that method, and using postal mail when preferred or necessary for transmittal of information and/or materials (printed and other). The first communication of CDPI system to a particular professional may necessarily be via postal mail. With that communication, the CDPI system queries the professional about preferences for future communications. The accumulation of such information enables communications with

5 increasing numbers of professionals according to their expressed preferences.

Information provided to the consumer-specified professional is product-specific and related to the disease state or health problem identified by the consumer. Further, by creating and maintaining a database record of each "inform my professional" transaction and of each
10 use of information resources by professionals, the CDPI system provides information to each professional which is appropriate to that professional's history of information use. For example, a professional who has previously received a consumer-directed communication about a particular product or disease state can, in a subsequent consumer-directed
15 communication about the same product or disease state, be reminded of the previous communication and be provided with a selected update of information, making the professional's task of topical review more efficient. Similarly, a professional prompted by that communication to make use of the CDPI system's Internet website information resources can be provided with information customized according to his or her prior use of the information resources. For example, product-labeling information may be displayed with text highlighting
20 of labeling changes made since the professional's last prior review of labeling information.

15 (m) Simultaneous with the Communication of Step (l). Inform the Professional of the Availability of Further Information or Service Resources Related to the Product or Disease State Specified in the Consumer's Request.

Optionally, the professional is also informed of and directed to other sources of
20 information (electronic, printed, etc.) and services (continuing education modules, meetings, manufacturers' representatives, product sampling, etc.)—via Internet website (of manufacturer, CDPI system, or other sources), postal mail (following request through any suitable medium, such as email, website, return postcard, toll-free "1-800" number, etc.), or other media. When appropriate (that is, to the marketing requirements of the manufacturer), access to such
35 information may be restricted to professionals who have been given electronic password, printed coupon, or other evidence of qualification for access to information or services through the CDPI system. It is anticipated that professionals' familiarity with these sources of information, developed through interaction with the CDPI system, will increase their responsiveness to the CDPI system's consumer-directed transactions and will also increase
40 their spontaneous, unprompted use of these sources.

30 (n) Create and Provide Information to Consumers and Professionals in a Manner that Maximizes Breadth of Information and Complies with Governmental Regulation of Marketing of Health Care Products.

45 The United States Food and Drug Administration (FDA) and other governmental regulations of prescription product marketing restrict and regulate the scope of information which may be provided by manufacturers to consumers or health care professionals. Information about "non-labeled" uses of products, that is uses that have not been approved by
50 the FDA, is particularly regulated. To maximize information service to consumers and professionals, the CDPI system optionally will coordinate the creation or compilation of

5 product-related information and services, including information written, edited, and presented
in a manner which maintains its editorial and physical separation from information and
services provided by product manufacturers, so that such information and services are provided
10 to consumers and health care professionals without violating governmental regulations. For
5 example, the consumer-directed communications to a specified professional can include
regulation-compliant marketing materials provided by the product's manufacturer and can also
include a message from the CDPI system to inform the professional of the availability (e.g., via
15 website or direct mail, etc.) of other information resources, including information which cannot
be directly disseminated by the product's manufacturer. Similarly, an Internet website
10 operated by the CDPI system can offer to consumers a range of information about products'
uses which exceeds the range of information which can be disseminated by the products'
manufacturers.

20 (o) Enable the Consumer to Indicate an Interest in Receiving the Names and Contact
Information for Conveniently Located Health Care Professionals Who Are Informed About
15 and Prepared to Consult About a Specific Product.

A consumer indicates interest in this CDPI service through media as described in step

25 (c).

(p) Enable a Consumer to Indicate A Health Care Specialty or Specialties or Disease State
20 Expertise of Interest in Finding Informed, Prepared Professionals.

30 In this optional step, for example, a particular product may be indicated for use in
treatment of more than one disease state, and such varied disease states may belong to the areas
of expertise of different professional specialists. For example, a beta-blocking medication may
be used by a cardiologist to treat cardiovascular disease and by a neurologist to treat migraine
headaches, or for both purposes by a primary care professional. In attempting to meet the
35 consumer's need for appropriate referrals, the CDPI system prompts the consumer for
information about the disease state or health problem of interest to the consumer and informs
the consumer regarding which professional specialties usually maintain expertise in diagnosis
and treatment of that problem. The consumer is then prompted to select the professional
40 specialty or specialties about which referral information is desired. The media for
30 communicating and displaying such information are as described in steps (d), (e) and other
steps.

45 (q) Enable a Consumer to Indicate a Locale in or Near Which He or She Prefers to Consult
with an Informed, Prepared Professional.

35 Through communications and display media as described above, the consumer
optionally may view information about locations of participating professionals who are
prepared to consult about the product or disease state of interest. The consumer is prompted to
indicate which geographic area is suitable for his or her access to a referral professional.

50 (r) Create and Maintain a Database of Information About Professionals Whose Preparation
for Disease- and Product-Related Consultation Meets Standards Established by the CDPI

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System.

An optional response to consumer requests for referrals requires an extensive database (or a plurality of databases) of participating professionals. Professionals will be receptive to referrals of consumers to them and they will, therefore, be willing to meet criteria established for participation. Such criteria are established, for example, by the product's manufacturer and may involve, for example, the professional's meeting with a manufacturer's representative to receive product-related materials, or attendance at a professional education meeting, or completion of an online (e.g., in Internet website) continuing education module about disease state diagnosis and treatment. The recruitment of professionals to participation is a function of the CDPI system, in which case the system builds and fills its own database of participating professionals. Alternatively, the manufacturer's sales force recruits participating professionals and directly or indirectly transfers information to the database. The database is established by the CDPI system or by the manufacturer; in either case, the CDPI system, in a preferred embodiment of the inventive process, effects direct electronic communication with the database to obtain information needed for response to consumer requests.

(s) Provide to the Consumer a List of Informed, Prepared Professionals who meet the Consumer's Stated Criteria.

In a preferred embodiment of the inventive process, the CDPI system effects direct electronic communication with the participating professionals database. Information about professionals appropriate to the consumer's inquiry is then provided to the consumer through an Internet browser and graphical interface in a personal computer system during the same website interaction session and immediately after the consumer communicates selection information to the CDPI system. Other communications media may be used, including nongraphical computer interfaces (e.g., email or alphanumeric displays), printed reports, postal mail, voice telephony, etc. Some such means of reporting may necessitate a delay between consumer request and provision of requested information. If there are insufficient numbers of participating professionals who meet the consumer's selection criteria, a partial listing may be given immediately and the system may prompt the consumer to give address information to allow delayed reporting. In such cases, the CDPI system can then act to recruit more participating professionals, either directly or through the product manufacturer, as described in step (r).

(t) Inform Each Professional of Consumer Inquiries and of Numbers of Consumers Given the Professional's Identifying Information.

This step will motivate professionals for prompt and timely review of product-related information and to motivate continued professional participation in the consumer referral activity. This can be accomplished through communications media appropriate to the professionals' individual communications capabilities and preferences. In a preferred embodiment, this occurs through Internet browser and graphical interface in the professional's personal computer system.

5 (u) Enable Consumers to Identify Health Care Systems or Health Insurers.

10 Fulfillment of the foregoing transactions requires building and filling a substantial database with information about the business names and operational territories of multiple insurance companies, health insurance products, and health care systems, and about these businesses' coverage or formulary inclusion of particular products. Such databases may be created and maintained by the CDPI system or by manufacturers or other parties, and the CDPI system requires access to such database(s) in order to respond to consumer requests for information. In a preferred embodiment of the inventive process, the consumer and CDPI system communicate with each other through Internet website and appropriate interfaces, as described above, and the CDPI system effects access to the database by direct and immediate electronic communications. The consumer is prompted to provide sufficient information about the insurance plan or health care system of interest, to allow the CDPI system to positively identify a single match in its database. This is similar to the process for positive identification of a specified health care professional from that CDPI database, as described in steps (e) and (f). Depending on the level of detail required to respond to the consumer's inquiry, the information required may include name of plan or system, geographical service area, consumer's insurance group number, consumer's employer, etc.

25 (v) Enable Consumers to Inquire About the Availability of Particular Products in the Insurance Coverage or Product Formularies of their Health Care Systems.

30 In the case of a consumer whose access to the CDPI system has been effected through a product-specific communication, the product specificity will be known to the system. In other circumstances (e.g., consumer access through a website with information about many products), the consumer will be prompted to indicate which product is of interest. Because insurance or health system coverage or formulary inclusion of a product may be related to disease state (i.e., covered for treatment of one disease state and not for another), the consumer may also be prompted to indicate which disease state or health problem is of interest. Given this information, the CDPI system can refer to a database of product coverage and formulary inclusion information and report to the consumer.

40 (w) Enable Consumers to View the Aggregated Expressions of Other Consumers' Preferences for a Particular Product, Generally and Related to the Health Insurers and Health Care Systems of the Inquiring Consumers.

45 The database of information about health insurers and health care systems will also include accumulated information about consumers' expressions of interest in particular products. This information can be displayed on request. For example, Mrs. Smith may wish to know how many other consumers have expressed preference, through the CDPI system, for coverage of a product's use. She may wish to know specifically how many other consumers covered by her health insurer or health care system also have expressed preferences for coverage or formulary inclusion of the product's use for a particular disease state. With this information, which constitutes an indication of aggregated consumer opinion, Mrs. Smith may

5 feel that she can approach the administrators of her insurance plan or health care system to call for consideration or reconsideration of coverage or inclusion of the product.

10 (x) Enable the Consumer to Express his/her Preference for Product Inclusion in Insurance Coverage, Formulary, and Add that Consumer's Expression of Preference to the Appropriate Database Categories.

5 This optional transaction allows the consumer to direct his/her expression of product-related preference. The expression of preference may include not only counts of "votes" for product coverage/inclusion but also text of consumer comments about product, health system experiences, and messages directed to other consumers, health insurers, or health system personnel. For example, Mr. Jones may wish to report to other consumers his experience with attempting to establish coverage for use of a product in treating his cancer. In a preferred embodiment of the inventive process, this is accomplished through Internet service access, web browser, graphical interface, and personal computer system in communication with the CDPI system's website services and information systems.

15 (y) Enable the Consumer to Send Messages, With or Without Personal Identification, to Personnel of Health Insurance Companies or Health Care Systems.

25 This transaction, similar to steps (j) and (k), allows consumers to direct comments about product coverage or formulary inclusion, through the CDPI system, to the attention of designated personnel of health insurers or health care systems. Such messages can be, at consumer discretion, posted in the CDPI system for other consumers to see. These transactions will require enabling consumer entry of or reference to names, titles, and addresses of the recipients of the messages and, in a preferred embodiment, the creation and maintenance of a CDPI database of designated personnel (e.g., pharmacy managers, CEOs, Pharmacy and Therapeutics Committee chairpersons, etc.) to whom such messages may be directed.

30 (z) Enable Consumers to Indicate Whether they Wish to be Informed about Future Events Regarding the Specified Product and the Specified Health Insurer or Health Care System.

35 The inventive process allows consumers to enter their addresses (email or other) in the CDPI system so that the system may later relay messages to them about requested information (about products, professionals, disease states, or health care systems) or from other interested consumers, while maintaining the consumers' addresses and identities as confidential information.

40 (aa) Enable Consumers to Send Messages to Groups of Similarly Interested Consumers to Share Information and Attempt to Form an Active Interest Group.

45 For example, Mrs. Smith may wish to organize and coordinate the activities of an interest/advocacy group regarding a product or related disease state for consumers in her health care system. The CDPI system can enable her to send a message (perhaps describing her interest, knowledge of the health care system's decision-making processes, proposals for action, and plans for an ongoing electronic discussion or actual meeting of consumers) to other interested consumers of Mrs. Smith's health care system who have given their addresses

(email, postal mail, etc.) to the CDPI system for that purpose. The CDPI system can relay such messages while maintaining consumers' addresses and identities as confidential. The CDPI system can continue to provide email communications or website display of information about the group's ongoing activities.

The foregoing process provides an opportunity to propose that manufacturers apply the CDPI system to the marketing of their products. The value to the manufacturers of the CDPI system in facilitating consumer-directed influence of product prescription will provide the major basis for the CDPI system's commercial success.

Figure Diagrams and Flow Charts

The inventive apparatus is illustrated in Figures 1, 2, 3, and 4. In a preferred embodiment, the present invention includes CDPI System Controller 400, Consumer's Interface Device 200 and CDPI System's Consumer Communication Support 2250, Professional's Interface Device 300 and CDPI system's Professional' Communication Support 2350, associated databases (Insurer and Health Systems Database Sources 2650, Professional ID Verification Database Sources 2600, and Participating Professionals Database Sources 2500), Product-Related Consumers' Interest Group Service 2700 accessible to Public Communication Devices 2750, and Product-Related Professionals' Interest Group Service 2800 accessible to Professionals' Communication Devices 2850. The present invention enables a product-interested consumer to direct CDPI system transactions to exert influence on the processes of health care product consideration, selection, formulary inclusion, insurance coverage, prescription, and consumer advocacy including consumer advocacy to governmental regulators and administrators. In a preferred electronic network (e.g., Internet) embodiment, the present invention renders provision of such service commercially feasible and practically convenient for consumer use.

Network Architecture

The components of a preferred embodiment of the present invention are illustrated in Figures 1 through 4. As illustrated in Figure 1, the apparatus of the present invention includes Consumer's interface Device 200, Central System Controller 400, and a Professional's Interface Device 300. These devices may communicate using one or more of such systems as postal mail, public telephone networks, the Internet, cellular and/or satellite data transmission links, etc.

As shown in Figure 2, Central System Controller 400 includes Central Processing Unit (CPU) 405, random access memory (RAM) 430, read-only memory (ROM) 440, clock 445, operating system 450, application software 455, cryptography processor 460, communications interface 470, and data storage device(s) 420.

A standard personal computer or computer workstation with adequate processing power and memory may be used as Central System Controller 400. In one embodiment it operates as a web server, receiving and responding to consumer requests 100 for access to CDPI services. Central System Controller 400 must be capable of rapidly performing database queries as well

5 as handling input and output needs. A Sun Microsystems 300 MHz UltraSparc II processor may be used for CPU 405. A similar processor such as a 500 MHz Compaq Alpha 21164 or 450 MHz Intel Inc. Pentium II may also be used.

10 Cryptography processor 460 may be configured as part of CPU 405 or utilize a
5 dedicated processor such as a Semaphore Communications Roadrunner 284 or VLSI Technology 6868. Cryptography processor 460 is used to encrypt potentially sensitive data during transfer between Consumer's Interface Device 200 and Central System Controller 400, as well as Professional's Interface Device 300 and Central System Controller 400.

15 Operating system 450 provides application software 455 with interface to CPU 405,
10 data storage devices 420, RAM 430, ROM 440, clock 445, and communications interface 470. In one embodiment, operating system 450 may be a commonly available system such as Sun Microsystems' Solaris 7. Possible alternatives include Microsoft Corporation's Windows NT Server or Compaq's Digital UNIX.

20 Application software 455 consists of software needed to carry out functions of central
15 controller 400. This software may include database management software, such as Oracle Corporation's Oracle8, web server software such as Netscape Communications Corporation's Enterprise Server, and custom-developed applications needed to handle consumer requests 100 for access to CDPI services.

25 Data storage device(s) 420 consist of storage media such as hard disk magnetic storage,
20 magnetic tape, or CD-ROM drives. Data storage device(s) 420 consist of databases used in the processing of transactions in the present invention. In the preferred embodiment, these databases consist of a Manufacturers/Products Database 421, a Sessions Database 422, a Transactions Database 423, a Consumers Database 424, a Doctors Database 425, a Participating Doctors Database 425, and a Health Insurers/Systems Database 427. Software
30 such as the aforementioned Oracle8 may be used to create and manage these databases. Data storage device also contains operating system 450 and application software 455.

35 Manufacturers/Products Database 421 contains data on products within the system for which information is made available by the CDPI system to consumers and professionals. It contains for each product multiple fields such as a unique key, product name, manufacturer,
40 product descriptive fields, pharmacological categories, disease state indications, text/images/layout of marketing materials, authoritative monographs, etc. This information can be entered by data transfer from manufacturer, or keyed entry by CDPI system personnel, or by other systems for data input.

45 Sessions Database 422 contains information about the timing and flow of each session
35 of interactive (in a preferred embodiment, online) communications between a consumer and CDPI System Controller 400. It contains information fields such as unique key, consumer identification number, times, date, options offered to and choices made by consumer, etc. This
50 enables tracking of system experience with various consumers and analysis of patterns of session events as related to variables in-format, sequencing, and content of the information and

5 service options offered to consumers. This information is automatically stored by application software 455 whenever an interactive communication session occurs.

10 Transactions Database 423 contains data on each interaction directed by the consumer and handled by the CDPI System Controller 400. It contains fields such as a unique key,
5 consumer identification number, time, date, and transaction type. The information in this database is primarily used for fulfillment of transactions directed by consumers and also enables historical or statistical tracking of transactions handled by the system. This
15 information is automatically stored by application software 455 whenever a transaction takes place.

20 Consumers Database 424 contains data on each consumer to have used the system. It contains fields such as a unique key, "cookies" placed in the consumer's computer memory by the CDPI System Controller 400, and any information provided by the consumer, such as
25 name, e-mail address, phone number, address, professionals, message texts, etc. The consumer, using Consumer's Interface Device 200, enters this information which is then stored
15 by the application software 455.

25 Professionals Database 425 contains data on all professionals with whom the CDPI system has had or has been directed to have contact. It contains fields such as a unique key, name, address, phone number, e-mail address, practice location, specialty type, disease states and products specified by consumers to be of interest, "cookies" placed in the professionals'
20 computer memories by CDPI System Controller 400, etc. This information may be entered by consumers in their contacts with CDPI System Controller 400 through Consumers' Interface
30 Devices 200, obtained by query of an external database (e.g., Professional ID Verification Database Sources 2600), entered by professionals in their contacts with CDPI System Controller 400 through Professionals' Interface Devices 300, entered by CDPI system
35 personnel through keyboard entry, transferred electronically from manufacturers' databases, etc.

40 Participating Professionals Database 426 contains information about doctors who have qualified for consumer referrals through the "Report Informed Doctors" Transaction (Figure 7). It contains fields similar to the Professionals Database 425, adding fields related to their
30 qualifications for referrals and their history of consumer referral transactions. This information may be entered by CDPI personnel, by doctors in the course of completing a qualifying activity such as an online product-related continuing education module, by electronic transfer from
45 manufacturers' data systems, etc.

50 Health Insurers/Systems Database 427 contains data on which health insurance
35 companies cover (provide reimbursement or payment for) which products. It contains fields such as a unique key, insurer name, geographic areas, plan and policy types, covered products, disease states indicating covered use, professionals participating in the plan, etc. Related to health care systems, similar information fields are filled and maintained, including formulary inclusion/exclusion information, criteria, text of available policies/procedures, etc. This

5 information may be entered by CDPI personnel, manufacturers' personnel, or electronic transfer from external data sources. It may include consumer-entered reports of experiences with insurers and health care systems.

10 Communications Interface 470 is the connection through which the central controller 5 400 communicates with Consumer's Interface Device 200 and Professional's Interface Device 300. In a preferred embodiment, Communications Interface 470 is connected using high-speed data lines such as T1 or T3 lines to the Internet. In this preferred embodiment, 15 communications will be handled by commercial web server hardware and software, assisted by custom software. Communications Interface 470 may also be configured other ways such as 10 an interactive telephone response system or electronic mail automated messaging system.

Although the above embodiment describes a single computer, the Central System 20 Controller 400 functions may be distributed across more than one computer system. In another embodiment, the central controller might consist of separate systems each handling a specific task, such as a database system and a web server system. Multiple systems may also be used in 15 each role to provide redundancy in case of connectivity or hardware failures.

25 Consumer's Interface Device 200 is the system by which a consumer interacts with the Central System Controller 400. In an ideal embodiment, the device is a traditional personal computer, comprised of input devices 280 such as keyboard and mouse, spoken voice input, and biometric or voice recognition devices to effect individual identification, as well as a CPU 20 205, RAM 230, ROM 240, operating system 250, video monitor 295, data storage device 220, and communications interface 270. The Consumer's Interface Device 200 may also be a 30 telephone, fax machine, or other communications equipment.

In the described Consumer's Interface Device 200 shown in Figure 2, central 35 processing unit 205, RAM 230, ROM 240, video driver 290, video monitor 295 must be any combination sufficient to run operating system 250 and applications software 255. 25 Communications Interface 270 may be a traditional modem, connected via standard telephone lines to the internet, or other means of communication such as Asymmetric Digital Subscriber Line (ADSL) or Integrated Services Digital Network (ISDN).

40 In a preferred embodiment, the consumer's personal computer would be running 30 application software 255 such as Netscape Communications Corporation's Communicator web browser, Microsoft Corp.'s Internet Explorer web browser, or other Hypertext Markup Language (HTML) compatible web browser. In other embodiments, the device might be a 45 similarly configured computer system interacting through an e-mail package such as Microsoft Corporation's Outlook or International Business Machines' Lotus Notes. In a preferred 35 embodiment, Professional's Interface Device 300 is essentially similar to Consumer's Interface Device 200 as described above.

Online Embodiment

50 In one embodiment of the present invention, communications between a consumer and the CDPI service system take place through electronic networks, with CDPI System Controller

5 400 acting as a network server. With reference to Figure 1, Consumer's Interface Device 200
is most often an Internet-connected personal computer, as diagrammed in Figure 2,
communicating by modem through a dial-up or other electronic link to the Internet and thereby
10 to Consumer Communication Support 2250. In this case the Internet webserver is controlled
5 by CDPI System Controller 400 via its communications interface 470. Alternatively, the
Consumer's Interface Device 200 could be a "smart" or "dumb" computer workstation on a
non-Internet network (e.g., a corporate intranet or a pharmacy chain's wide area network),
communicating with a network server which in turn communicates with Consumer
15 Communication Support 2250 and CDPI System Controller 400 through non-Internet or
10 Internet channels. In any case, "online" implies that the consumer has a real-time, interactive
connection to CDPI System Controller 400, enabling the consumer to send a variety of
instructions and information 100 to it, including the initial instruction to provide information
20 and access to CDPI services and subsequent instructions, and enabling the consumer to receive
information from CDPI System Controller 400. The same Consumer's Interface Device 200
15 enables online communication with Product-Related Consumers' Interest Group Service 2700,
which may be operated in cooperation with CDPI Service but not necessarily under the control
25 of CDPI System Controller 400.

A consumer initiates contact with CDPI Service Controller 400 through any of several
online strategies. The consumer may have used an Internet search engine service (such as
20 Yahoo! or Alta Vista) to find a specific health care product by name, then chosen to visit a
30 particular website. The consumer may have visited a website, perhaps one controlled by CDPI
Service Controller 400, known for its comprehensive offerings of information and services
related to health care products. Or the consumer may have searched for information about a
particular health or disease state and then, finding that a product may be indicated for
35 25 treatment, linked to product-specific information. Alternatively, the consumer, having become
aware of the Internet URL of a product-specific website as a result of the manufacturer's
direct-to-consumer product marketing, has visited that website. In any of these contexts, the
consumer is given information about and an invitation to use CDPI services. The consumer's
40 positive response to that invitation results in Consumer's Interface Device 200 being linked
30 directly to a CDPI service website or in being simply "windowed through" to the CDPI
service's functions without technically "leaving" the Internet browser connection with the
originating website. For example, a manufacturer's product-specific website may offer CDPI
45 services to visiting consumers and then facilitate a consumer's interaction with Consumers'
Communication Support 2250 and CDPI Service Controller 400 through a "window" in the
35 product-specific website, and then maintain connection with the consumer upon closing of the
"window" after completion of interactions with CDPI Service Controller 400.

Continuing with description of the online embodiment of the CDPI System
50 diagrammed in Figure 1, it is seen that CDPI Controller 400 is in electronic communication
with sources of information needed to complete consumer-directed transactions.

Communication links may be local or distant, networked, Internet-mediated, or otherwise. The information sources include:

Professional ID Verification Database Sources 2600 are the sources of information about professionals' names, academic qualifications, licensure, specialties, addresses, phone numbers, etc. For example, the AMA maintains and frequently updates such a database for all MDs and DOs in the United States; it is made available on a subscription basis online or on CD, through several vendor companies. Similar databases are available for other categories of health care professionals. Professionals Database 425 (Figure 4) is filled with information derived from queries of Professional ID Verification Database Sources 2600 and from CDPI System Controller 400 interactions with consumers and professionals via their interface devices 200 and 300.

Participating Professionals Database Sources 2500 are the sources of information about which doctors are participating in product-related consumer referral programs (*i.e.*, which doctors have met CDPI system criteria as informed or experienced in the use of a product, willing to receive new consumer referrals, etc.). The sources of such information would typically be the products' manufacturers. For example, a manufacturer's sales force may report participating doctor information to Participating Professionals Database Sources 2500 via interfaces including Internet-connected computers, telephone message system, etc. Alternatively, a doctor may be invited to qualify as a participating professional by completing a continuing education program (online or otherwise) which includes information about the product and the disease state(s) for which it is indicated. A manufacturer may independently maintain a database of participating professionals and make it available on a network or secure Internet server functioning as Participating Professionals Database Sources 2500 for CDPI System Controller 400 to query as needed. Alternatively, server 2500 may be a part of the CDPI system's information system. In any case, Participating Doctors Database 426 (Figure 4), internal to CDPI System Controller 400, is filled with information obtained by queries of Participating Professionals Database Sources 2500.

Insurer and Health Systems Information Database Sources 2650 are the sources of information about health insurers' and health care systems' coverage and formulary inclusion policies concerning particular products. Typically, this information is provided by manufacturers as a consequence of the information gathering activities of their sales forces. Alternatively, it is provided by consumers' reports of experience with their insurers and health care systems, or it may be legally mandated that insurers and health care systems make such information open to the public. Server 2650 may be controlled by CDPI System Controller 400 or may be independently maintained and is, in a preferred embodiment, available through network or other automated connection for CDPI System Controller 400 to obtain information as needed by query. Health Insurers/Systems Database 427 (Figure 4), internal to CDPI System Controller 400, is filled with information obtained by such queries.

CDPI System Controller 400 is in communication with Product-Related Consumers'

Interest Group Service 2700, to facilitate consumer access to product-related information and to CDPI system services. For example, a consumer who has interacted with an interest group website 2700 may be informed about and linked or "windowed" to CDPI system services. A consumer who has made use of CDPI services may be informed about and linked by request to an interest group (e.g., disease state, health system advocacy, or product buyers' club). In a preferred embodiment, Product-Related Consumers' Interest Group Service 2700 is accessible to consumers by Public Communication Devices 2750 which include Internet-ready personal computers, network workstations, automated or voice telephony, direct mail, etc., meeting the needs of a variety of consumers and situations.

Similarly, CDPI System Controller 400 is in communication with Product-Related Professionals' Interest Group Service 2800, to facilitate fulfillment and effectiveness of consumer-directed transactions with CDPI System Controller 400. For example, a consumer's "Inform Professional" transaction results in a CDPI System Controller 400 communication with the consumer-specified professional. This communication includes information about the product of interest to the consumer and directs the professional to information and service resources available through Product-Related Professionals' Interest Group Service 2800. In a preferred embodiment, the professional then connects to service 2800 via an online connection (Professional's Communication Device 2850) to obtain such additional product-related information and services. Alternative embodiments allow for such transaction fulfillment and interest group communications to occur, as needed, by telephone, fax, postal mail, etc.

Consumer-Direct Prescription Influence Process

A preferred embodiment of the CDPI process, including both essential steps and optional steps, is described in Figures 5-11. Figure 5 shows the overall process for a consumer-initiated transaction or transactions over an Internet means of communication with a CDPI website. With reference to Figure 5, a consumer will initiate gathering of information about a product or a particular disease state from any number of means 500, such as product website, broadcast advertisement, print advertisement or referral. The product information source provides a means for the consumer to influence his or her professional or health care system to allow the consumer to obtain a particular product or service of interest. Such a means is referral or link to a CDPI website 510 through a referral web address or direct link to a CDPI website server.

The consumer is then linked to a CDPI website process and can choose to begin a transaction or simply be informed of the various professional inform or health care system inform transaction services provided through such a site. The consumer chooses to initiate a transaction session 520 and a session record is initiated in a sessions database 422. The consumer selects various options available, as described herein, and proceeds with the transaction 530. Such transaction can be a simple one of informing the consumer's professional (e.g., primary care physician in a health maintenance organization (HMO)) of an upcoming visit and desire to consult about the possible use of a new pharmaceutical, e.g.,

5 Viagra®. The CDPI process "informs" the selected professional of the upcoming visit,
preserves consumer confidentiality if requested, and provides product information to the
professional if the professional so desires. Alternatively, or in addition, the CDPI process can
10 initiate and complete a transaction that will refer the consumer to a professional in the
5 consumer's chosen geographical area who has been informed about a particular product of
interest and can see the consumer to evaluate the consumer for a prescription. Once a
transaction is completed, the CDPI process asks the consumer if another transaction should be
conducted. If there is another transaction, the CDPI process resets the transaction sequence
15 540, displays the next selected transaction and initiates an additional transaction record in the
10 transactions database 423. Alternatively, the session can be completed 570, wherein the
session is recorded 580, and the consumer is optionally returned to the Internet product
information source 590.

20 With regard to Figure 6, this sets forth the process for informing a professional about a
particular product or service when the consumer wishes his or her professional to be aware of
15 the product or service and plans to discuss it at an upcoming appointment with the
professional. The consumer first confirms his or her interest 610 and the transaction
25 instructions appear 620. The consumer gives the information he or she is aware of for the
particular professional (doctor) 630. A professional database 425 is queried 631 to provide a
match for a professional with the information the consumer provided. The professional
20 information is corrected as needed and the identification of the professional is confirmed 632.
30 The consumer then provides information for the disease state(s) of interest relating to the
product 640 and the anticipated time frame of an appointment with the professional 650. The
consumer then has a choice of whether or not to identify himself or herself 660 and if the
consumer decides to identify himself or herself, a message block to the professional is
35 25 provided 665. The consumer can also send a message to the professional without identification
as to the identity of the consumer 670, 675. The consumer is provided with the transaction
service terms and conditions 680 and the consumer is given a final chance to review the
transaction before it is completed 690.

40 With regard to Figure 7, a consumer becomes aware of a product or service that can
30 only be prescribed by a professional and desires to visit an informed local professional who
can consult and might prescribe it for the consumer. The consumer obtains information about
the product or service of interest 710 and is informed about a service to provide the identity of
45 professionals who have also become aware of the product or service of interest 720. The
consumer can query a participating professionals database 426 based upon consumer-selected
35 criteria 730 and the appropriate database 426 is queried 740 and matches, if any, are displayed
750. If the matches are insufficient, the selection limitations are displayed and an opportunity
to change selection criteria is provided 752, or an opportunity for a delayed report 754. If the
50 consumer revises the criteria, such as scope of geographic area 756, the revised criteria are
displayed 730 and the participating professionals database 426 is again queried and results

5 displayed 740. The consumer is informed of the transaction service terms and conditions for a report of informed professionals about a particular product or service 760, and the report is displayed for the consumer 770 in a printable form if the consumer so chooses.

10 5 Figure 8 shows a consumer-directed "express preference" transaction. This type of transaction enables the consumer to express his or her preference to a health care system (HMO, medical insurance provider, etc.) regarding a particular product or service which could be covered or included in the relevant formulary. This transaction also provides information to the consumer, if available, regarding whether a particular product is covered by a particular health care system program at the present time. This transaction process can begin by the consumer expressing an interest in the particular product or service 810. A product-specific website can provide a link to a CDPI website and an option to communicate with or about one's health care system is an option for a consumer transaction. If notifying ones health care system is selected as a transaction 820 after information about it is displayed, the consumer provides information about the health insurer or health care system 830. Once such information is entered, the health insurers/systems database 427 is queried to match the consumer-provided information 840. The information is displayed for customer verification 845 if there is a match with the database 427. The consumer is then prompted to express preferences 850 (and optionally enters them 855), to identify self 860 (and optionally identifies self through ID 865), to enter a message 870 (and enters message to health care system 875), and to provide the consumer's address and contact information 880 (and optionally provides such information 885). The consumer is then provided with transaction terms and conditions 890 and, if accepted, the results of the expressed preference are provided to the consumer 895.

35 25 The present inventive process also provides a means for obtaining a positive identification of the consumer for verification purposes and still provides a means for preserving the consumer's confidentiality from professionals, product or service manufacturers or providers, and the health care systems, if the consumer so chooses. In Figure 9, a consumer chooses a self ID 910 and then the consumer optionally can choose to display information about the consumer ID function 920, accept terms of consumer ID function 930, providing consumer identifying information 940, and displaying and confirming, by the consumer, such identifying information 945. Similarly, and further illustrated in the flow chart on the right side of Figure 9, a consumer can optionally choose a message 950 and then optionally choose to receive information about a message function 960, accept or reject terms of a message function 970, select addresses for sending the message 980 (such as health insurance carriers, HMO, professionals, or even the manufacturers of the product), provide the message 990, and then review and confirm both the addresses and the text of the message to be sent 995.

50 35 Similarly, the consumer can choose whether or not the consumer wishes to receive messages in reply to those sent in the optional process described in Figure 9. Again, such messages can be sent with or without identifying characteristics of the consumer, at the choice of the consumer. If a consumer chooses to receive a message 1010, information about the

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5 message receive function is displayed 1020, the consumer then accepts the terms of the receive function 1030, and if so accepted the consumer is prompted to receive message categories 1040, the consumer provides (or directs creation of) addresses 1050, and the consumer confirms instructions and addresses of senders of messages to be received 1055.

10 5 In each of the foregoing transactions illustrated in Figures 5-9, a database is queried, selected from the group of databases shown in Figure 4 421-428. The process for reference database checking, depending upon the specific transaction selected, is shown in Figure 11. Specifically, a reference database query request message 1110 is automatically linked to a
15 central server 1120 and then shunted to either a automated reference database 1130 and the proper specific database of the selected transaction, or is sent to a person in the CDPI system
10 for direct query to the relevant database 1140. The response is provided 1150 and returns to the appropriate consumer interface, such as through an Internet website or even a telephone
20 connection.

Claims

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I claim:

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1. A process for process for facilitating consumer and professional interaction and communication about products and services that require a professional decision before a consumer can purchase or be prescribed a particular product or service by a professional or (2) facilitating the marketing of regulated products by manufacturers to professionals, consumers and health care systems, or (3) providing consumers with a means for influencing decisions of professions and health care systems with respect to providing a product or service and having the product or service available with a particular health care system program, the process comprising the steps of:

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10 (a) providing a direct-to-consumer and professional health care product or service information source having a connection or a link to a transaction-based consumer, professional and manufacturer product or service communication service;

20

(b) providing the transaction-based consumer and manufacturer product or service communication service having a consumer transaction menu listing potential transactions selected from the group consisting of (i) informing a professional about a consumer's interest in a particular product, service or disease state, (ii) providing the professional with information about the particular product or service, (iii) providing the consumer with identification of professionals who have been informed about a particular product or service, (iv) providing consumers with a means for communicating health care product or service preferences and desires to health care systems and professionals who have the means or authority to prescribe, specify, authorize, cover (bear the cost of), restrict, prohibit or exclude products for use by consumers and reimbursing for covering the costs of such health care products and services, (v) providing the means for consumers to aggregate and express their preferences and to form interest groups to influence health care systems and professionals with regard to consumer availability of products and services, (vi) providing the means for the consumer to communicate with appropriate governmental regulators or administrators of such products or services, and combinations thereof; and

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(c) allowing a consumer an ability to complete one or a plurality of transactions.

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2. The process for facilitating consumer and professional interaction and communication about products and services that require a professional decision before a consumer can purchase or be prescribed a particular product or service by a professional of claim 1 wherein the transaction-based consumer and manufacturer product or service communication service further provides the consumer the means for providing his or her identity to manufacturers, professionals and health care systems or not providing his or her identity to any or all of the selected manufacturers, professionals and health care systems.

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3. The process for facilitating consumer and professional interaction and communication about products and services that require a professional decision before a consumer can purchase or be prescribed a particular product or service by a professional of claim 1 wherein the informing the health care professional about a consumer's interest in a

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5 particular product, service or disease state transaction (ii) provides the professional with information from the manufacturer of the product or service, such information from the manufacturer having been approved by an appropriate regulatory agency.

10 4. The process for facilitating consumer and professional interaction and communication about products and services that require a professional decision before a consumer can purchase or be prescribed a particular product or service by a professional of claim 3 wherein the information provided to the professional is supplemented by independent (of manufacturers) research concerning the product, service or disease state from published medical literature.

15 5. The process for facilitating consumer and professional interaction and communication about products and services that require a professional decision before a consumer can purchase or be prescribed a particular product or service by a professional of claim 3 wherein such information is supplemented by product coupons or vouchers for consumer use, and provision of such materials is coordinated with provision of product samples to the consumer's identified health care professional by mail or by a manufacturer's sales representative.

20 6. The process for facilitating consumer and professional interaction and communication about products and services that require a professional decision before a consumer can purchase or be prescribed a particular product or service by a professional of claim 1 wherein the transaction (ii) to provide information about a consumer's interest in a particular product, service or disease state further comprises the step of consulting a manufacturer's/products database to determine if a participating manufacturer subscribes to the transactions service.

25 7. The process for facilitating consumer and professional interaction and communication about products and services that require a professional decision before a consumer can purchase or be prescribed a particular product or service by a professional of claim 1 wherein the transaction (ii) to provide information about a consumer's interest in a particular product, service or disease state further comprises the step of consulting a professionals database to determine if a professional selected by the consumer is known in the database as a licensed professional able to authorize the service or prescribe the product selected.

30 8. The process for facilitating consumer and professional interaction and communication about products and services that require a professional decision before a consumer can purchase or be prescribed a particular product or service by a professional of claim 1 wherein the transaction (iii) to provide the consumer with a list of professionals who have been informed about the selected product or service further comprises the step of consulting a participating professionals database to find a list of professionals who have met criteria for inclusion in a referral system.

35 9. The process for facilitating consumer and professional interaction and

5 communication about products and services that require a professional decision before a
consumer can purchase or be prescribed a particular product or service by a professional of
claim 8 wherein the list or professionals provided to the consumer are further selected on the
10 basis of listed geographic area taken from addresses or other content of data fields in the
professionals database.

15 10. The process for facilitating consumer and professional interaction and
communication about products and services that require a professional decision before a
consumer can purchase or be prescribed a particular product or service by a professional of
claim 1 wherein the transaction (iv) to inform either or both of a consumer's health care
10 professional or health care system of the consumer's desire and need to have a particular
product or service available to the consumer under the consumer's health care system, further
comprises the step of consulting with a health insurer/systems database to insure that the
consumer's preferences and messages are correctly transmitted to the specified recipient.

20 11. The process for facilitating consumer and professional interaction and
communication about products and services that require a professional decision before a
consumer can purchase or be prescribed a particular product or service by a professional of
claim 1 wherein the transaction (v) to make other consumers in a relevant interest group aware
25 of a product or service to aggregate such consumers into an interest group further comprises
the step of enabling communication among or identifying consumers to each other but not
necessarily to the health care system or professionals.

30 12. An apparatus or server system for implementing the transaction-based consumer
and manufacturer product or service communication service over a wide area network, Internet
or over telephone and mail means of communication, wherein the server system comprises a
central processing unit, ROM, RAM, and a data storage device, wherein the data storage
35 device comprises one or a plurality of databases selected from the group consisting of a
manufacturers/products database, a consumers database, a professionals database, a
participating professionals database, a health insurers/systems database, and combinations
thereof.

40 13. The apparatus or server system for implementing the transaction-based
consumer and manufacturer product or service communication service over a wide area
network or over telephone and mail means of communication of claim 12, wherein the
apparatus or server system data storage device further comprises one or a plurality of a
sessions database, a transactions database, a CDPI process reference database, and
45 combinations thereof.

50 14. The apparatus or server system for implementing the transaction-based
consumer and manufacturer product or service communication service over a wide area
network or over telephone and mail means of communication of claim 12, wherein the
apparatus or server system data storage device is able to complete transactions i through vi and
comprises each of the manufacturers/products database, the consumers database, the

5 professionals database, the participating professionals database, and the health insurers/systems
database and wherein the transactions are selected from the group consisting of (i) informing a
10 professional about a consumer's interest in a particular product, service or disease state, (ii)
5 providing the professional with information about the particular product or service, (iii)
providing the consumer with identification of professionals who have been informed about a
particular product or service, (iv) providing consumers with a means for communicating health
15 care product or service preferences and desires to health care systems and professionals who
have the means or authority to prescribe, specify, authorize, cover (bear the cost of), restrict,
prohibit or exclude products for use by consumers and reimbursing for covering the costs of
10 such health care products and services, (v) providing the means for consumers to aggregate and
express their preferences and to form interest groups to influence health care systems and
professionals with regard to consumer availability of products and services, (vi) providing the
20 means for the consumer to communicate with appropriate governmental regulators or
administrators of such products or services, and combinations thereof.

15 15. The apparatus or server system for implementing the transaction-based
consumer and manufacturer product or service communication service over a wide area
25 network or over telephone and mail means of communication of claim 14, wherein the
apparatus or server system data storage device further comprises one or a plurality of a
sessions database, a transactions database, a CDPI process reference database, and
20 combinations thereof.

1/11

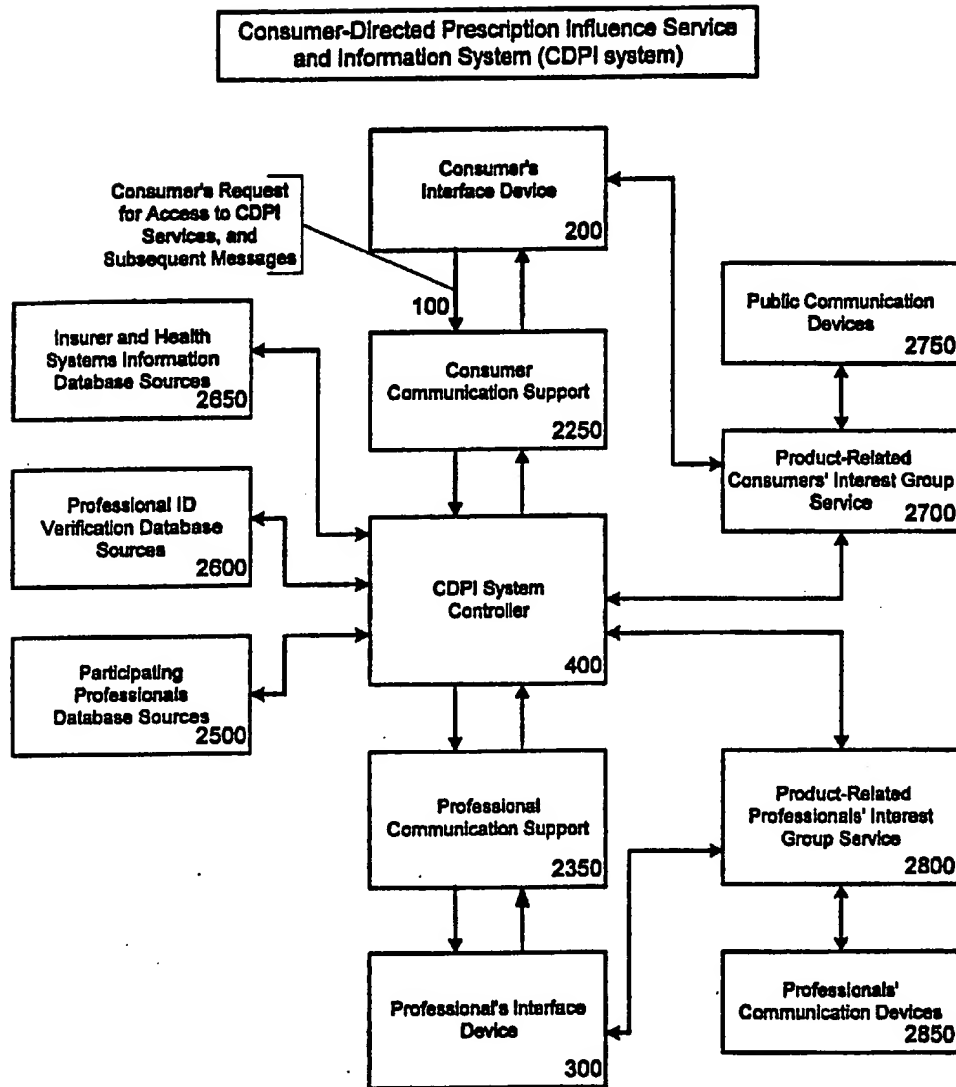


Figure 1

2/11

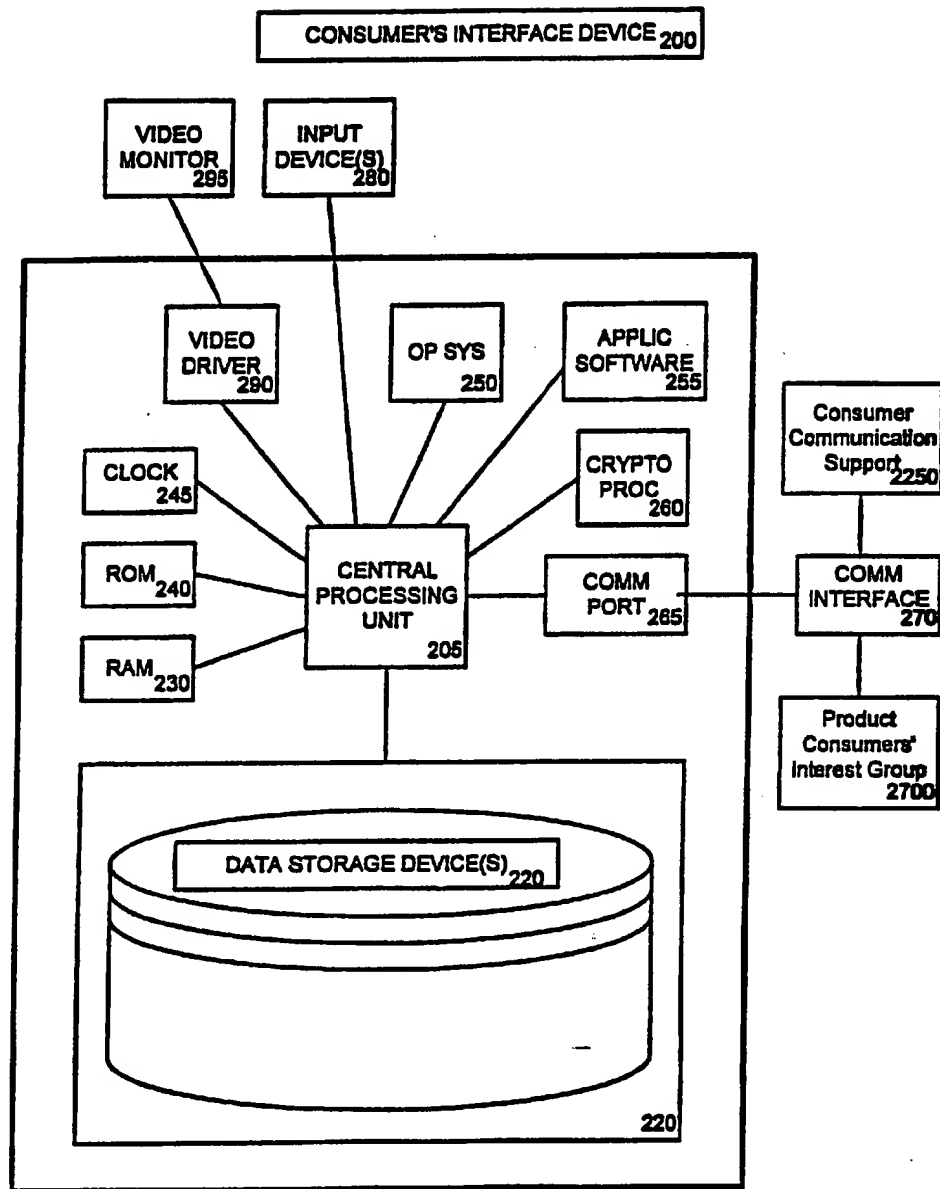


Figure 2

3/11

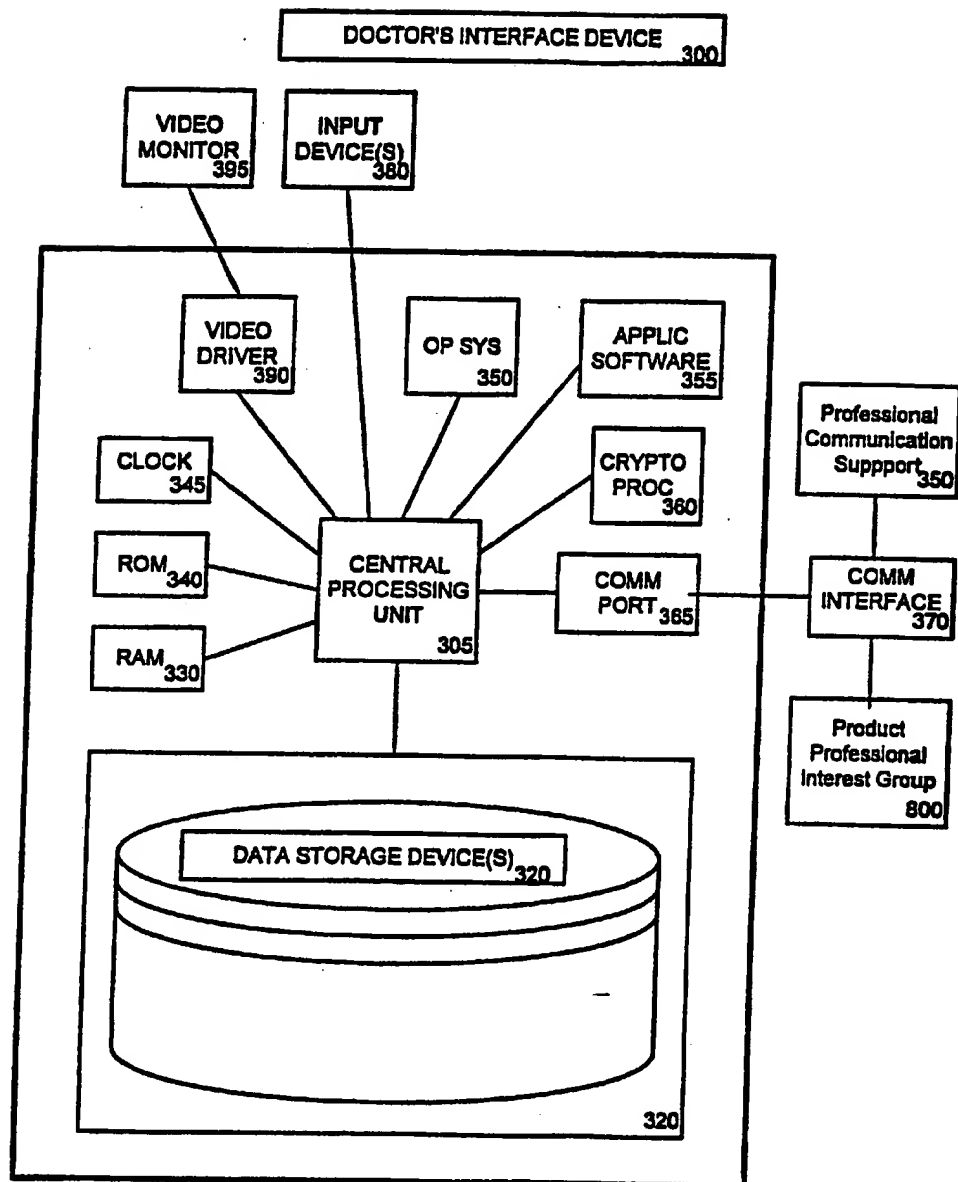


Figure 3

4/11

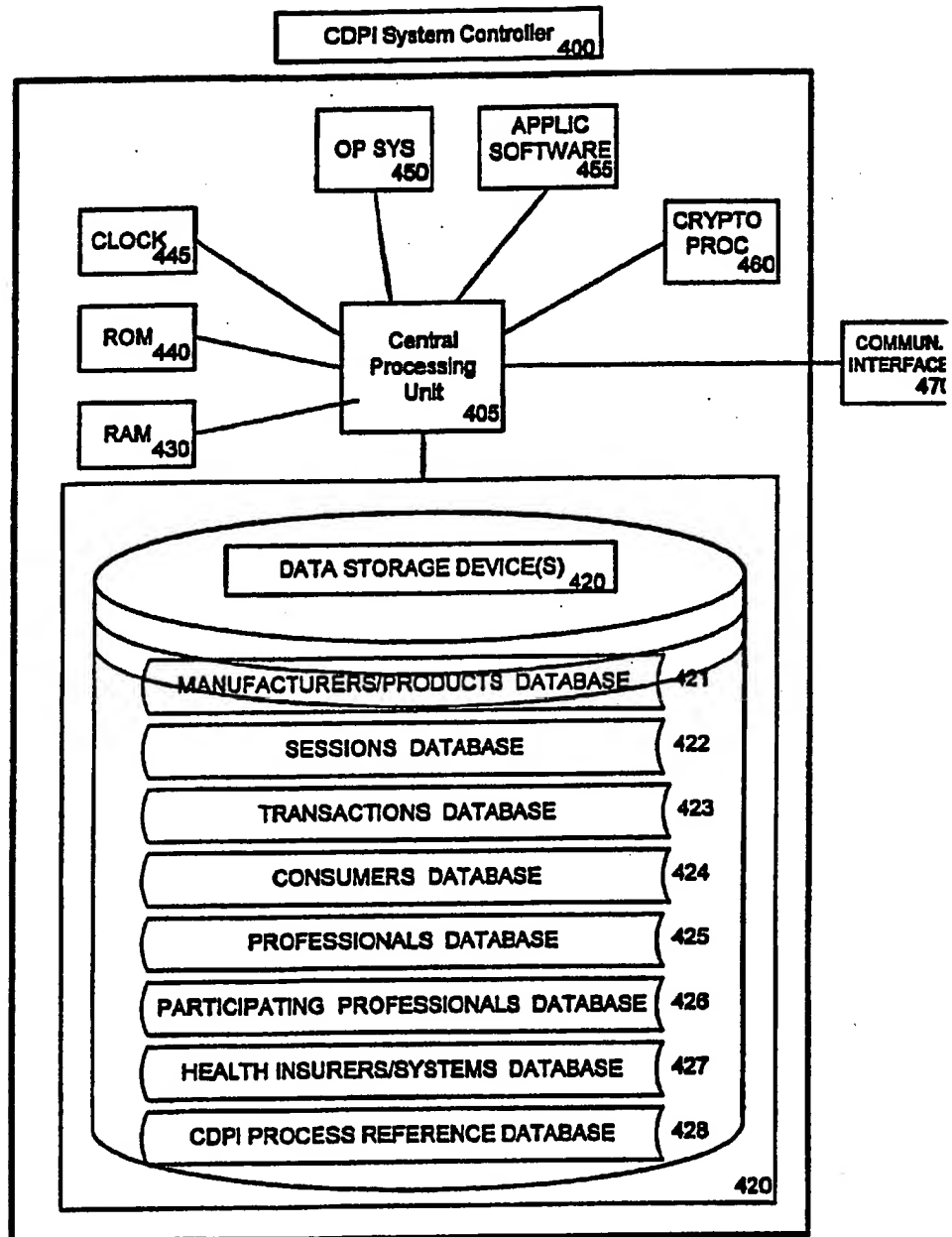


Figure 4

5/11

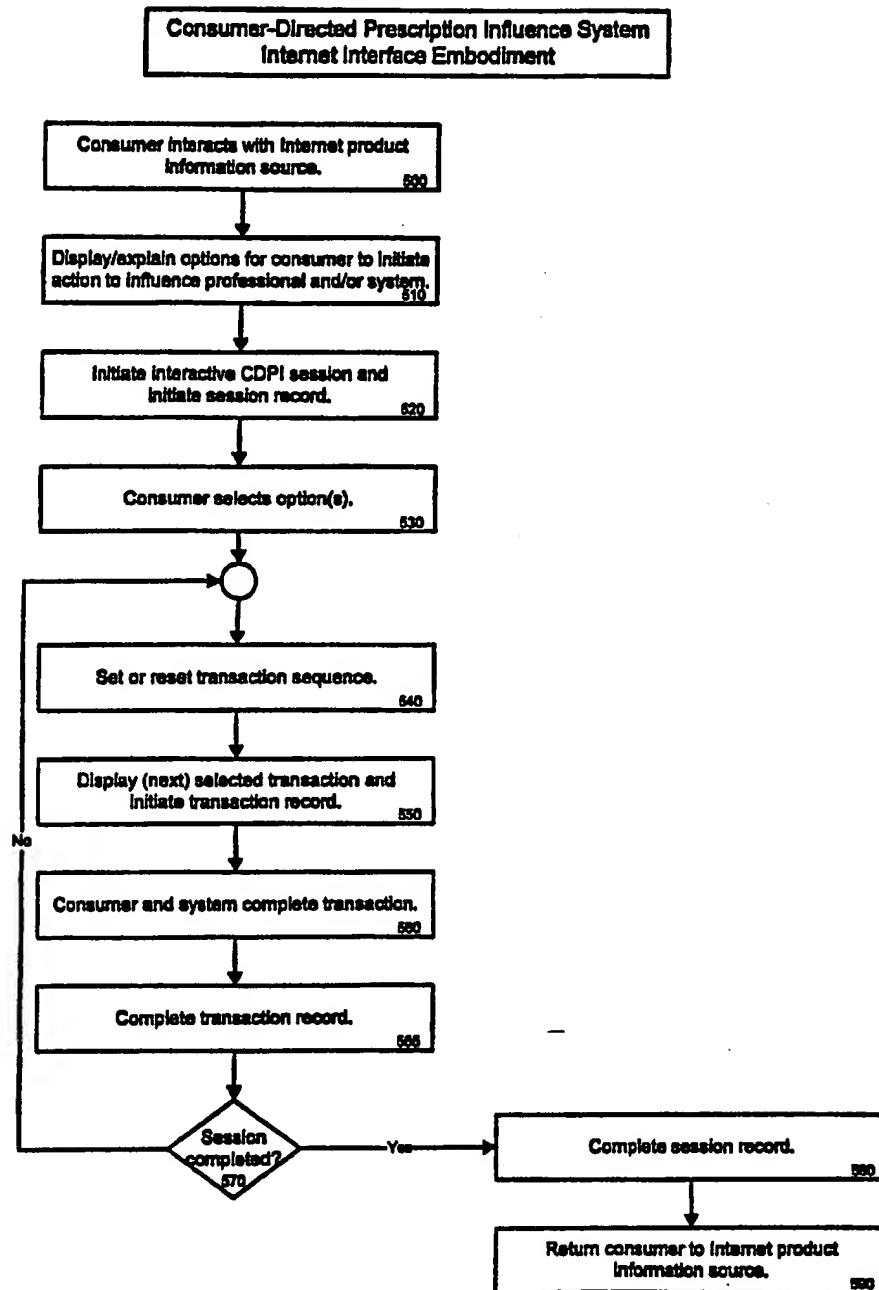


Figure 8

6/11

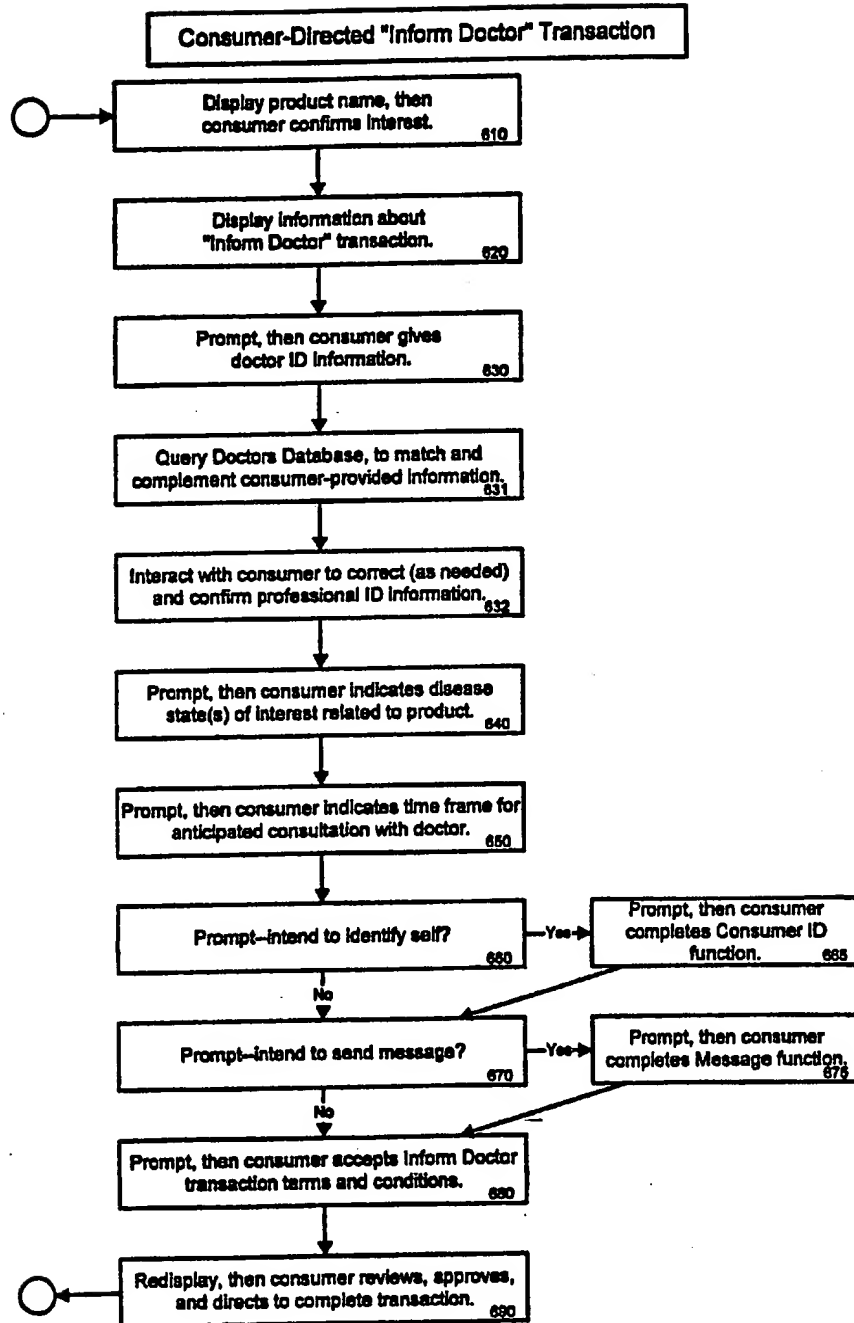


Figure 6

7/11

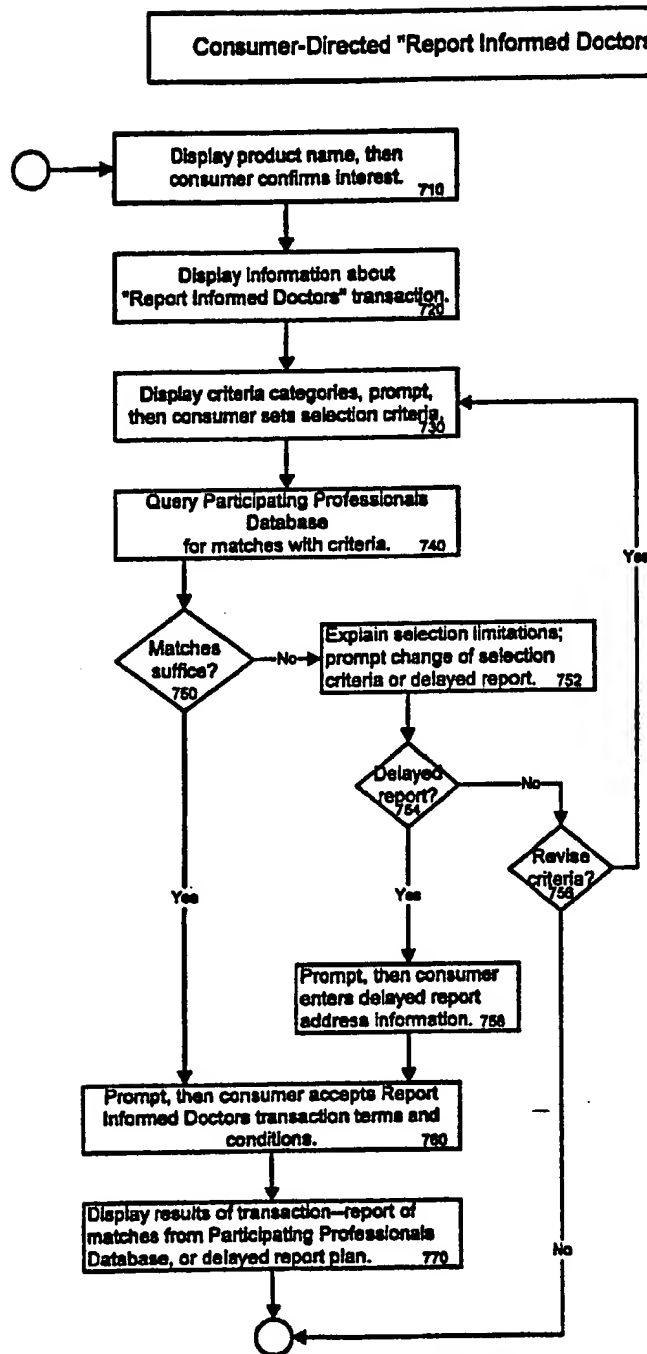


Figure 7

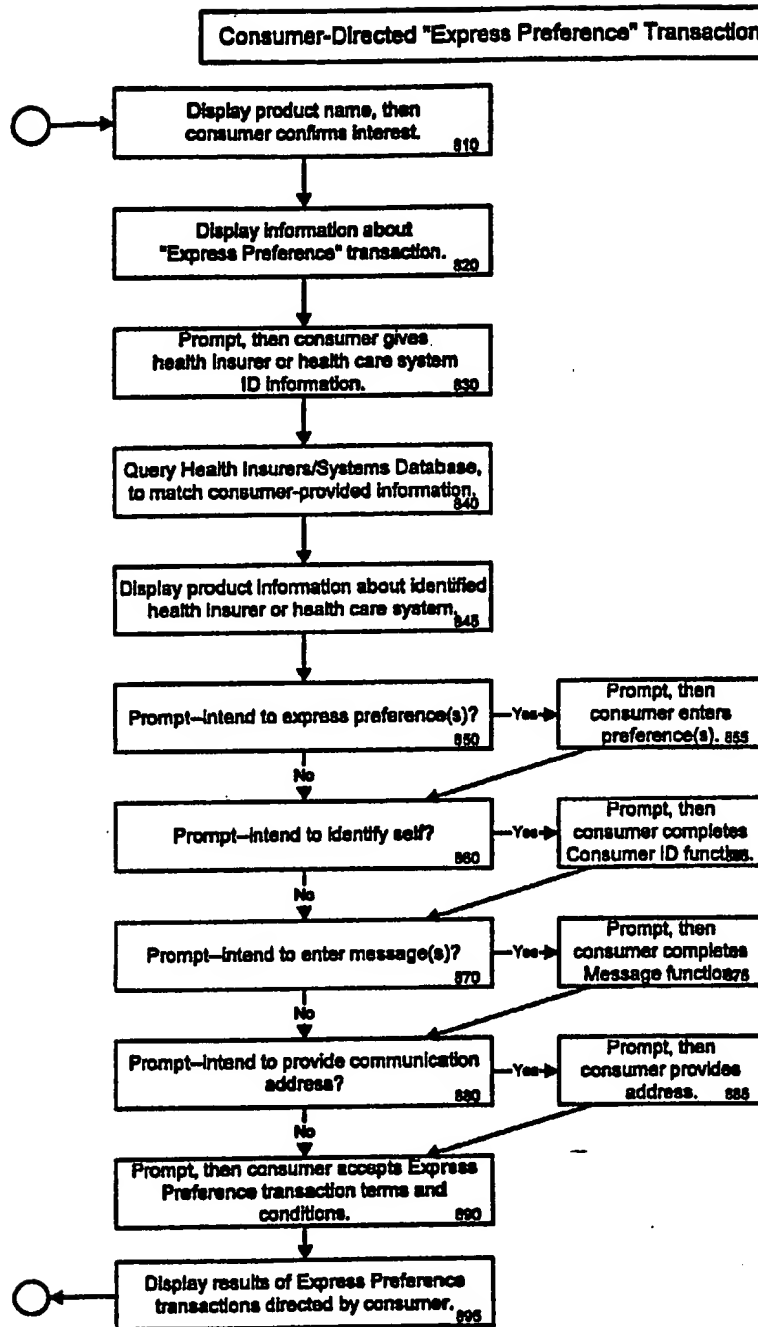


Figure 8

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CDPI System - Consumer ID & Message Functions

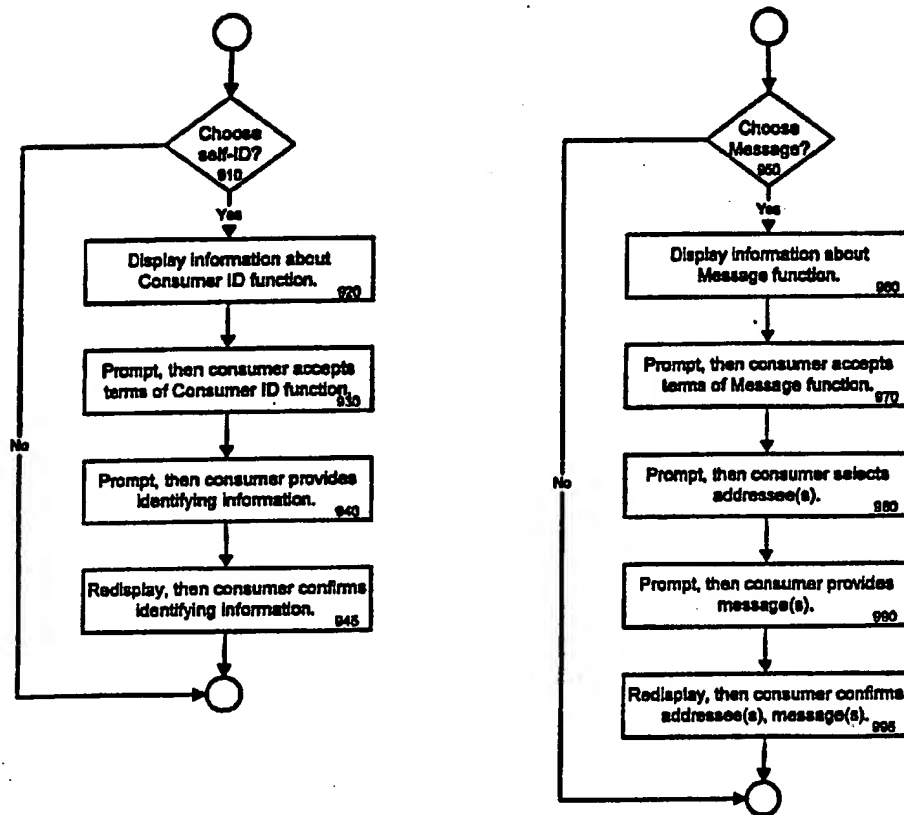


Figure 9

CDPI System - Consumer Receive Function

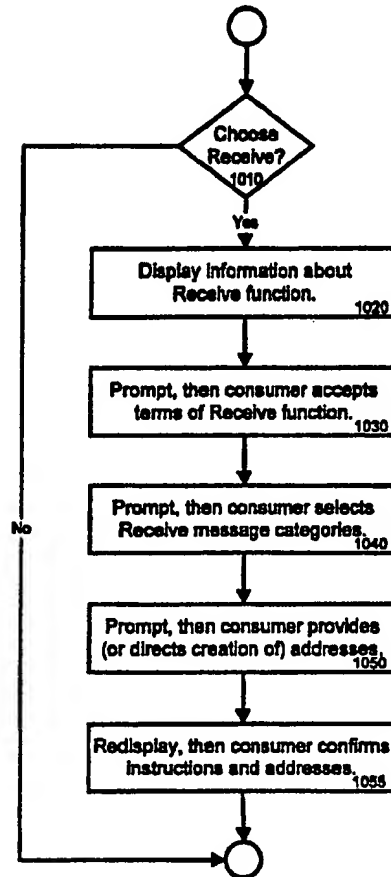


Figure 10

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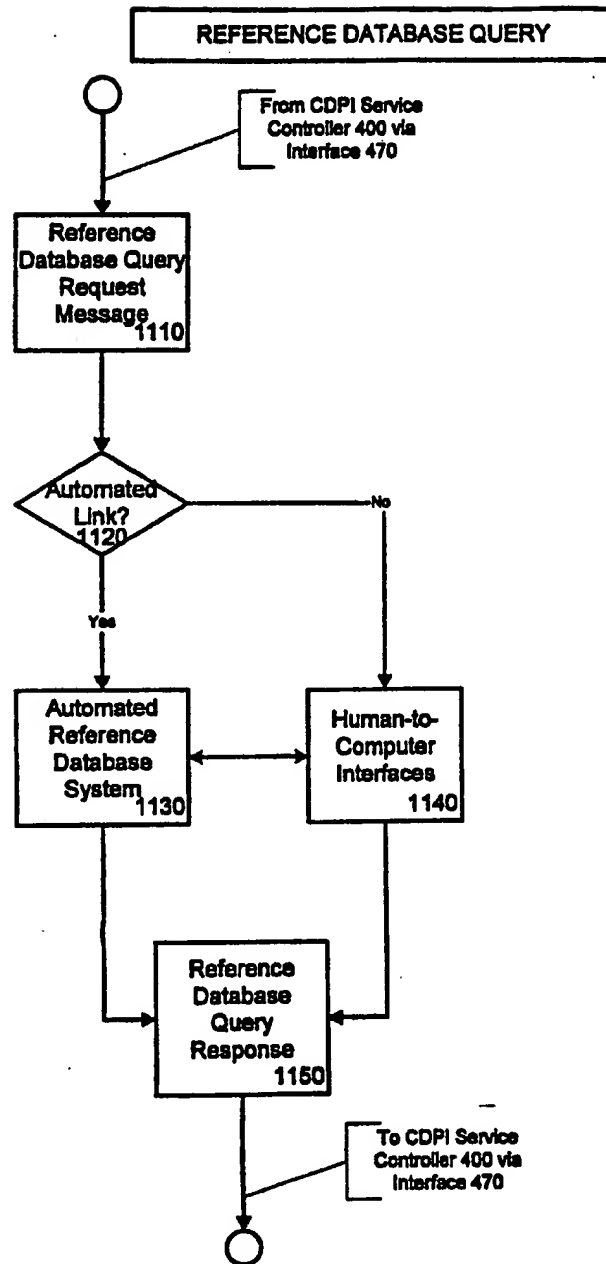


Figure 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/31210

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G06F 17/60

US CL : 705/2

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 705/2; 380/25; 707/5, 102; 600/300

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P — Y	US 5,964,700 A (TALLMAN et al.) 12 October 1999, col. 3, lines 46-60; col. 5, lines 5-25; col. 7, lines 8-32; col. 11, lines 4-67; col. 12, lines 1-67; col. 13, lines 1-48; col. 14, lines 15-32; col. 15, lines 53-56; col. 36, lines 53-67; col. 40, lines 3-16; col. 48, lines 60-67; col. 49, lines 1-28.	1-10, 12-15 ——— 11
Y,E	US 6,012,035 A (FREEMAN, JR. et al.) 04 January 2000, col. 4, lines 12-24.	11
A,P	US 5,862,223 A (WALKER et al.) 19 January 1999, abstract.	1-15
A,E	US 6,018,742 A (HERBERT, III) 25 January 2000, abstract.	1-15

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

10 MARCH 2000

Date of mailing of the international search report

26 APR 2000

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/31210

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US 5,983,220 A (SCHMITT) 09 November 1999, abstract.	1-15
A,E	US 6,014,629 A (DeBRUIN-ASHTON) 11 January 2000, abstract.	1-15
A,P	US 5,867,821 A (BALLANTYNE et al.) 02 February 1999, abstract.	1-15